Study id: **Extractor initials:**

Date:

Study ids of linked reports:

Aim of study:

Study design:

☐ *RCT*
☐ *Non-randomised comparison*
☐ **Prospective/Retrospective cohort** (please underline)

Multicentre study? ☐ *Yes* *If Yes number of centres:*
☐ **No**

Length of follow-up:

Study start/end dates: **Duration of study:**

Country:

Source of funding:

Additional information on study design:

Types of participants:

☐ **Women without detectable metastatic disease who have received breast conserving surgery for primary breast cancer**

☐ **Women without detectable metastatic disease who have received mastectomy for primary breast cancer**

Type of Intervention /Comparator

RCT/Comparison Studies

- ☐ **SM versus No formal direction or contact with a health care professional**
- ☐ **SM versus Alternative follow up regimen** (please state regime)
- ☐ **Differences in frequency of SM regimens**

Cohorts:

- ☐ **Surveillance Mammography**
- ☐ **Alternative follow up regimen** (please state regimen)

Outcomes reported:

☐ **IBTR**

- ☐ **Overall survival**
- ☐ **Disease free survival**
- ☐ **QOL**
- ☐ **Harms of mammography**
- ☐ **Uptake of mammography**

☐ **MCBC**

- ☐ **Overall survival**
- ☐ **Disease free survival**
- ☐ **QOL**
- ☐ **Harms of mammography**
- ☐ **Uptake of mammography**

Participant Characteristics

Study inclusion criteria:

Study exclusion criteria:

	Group 1	*Group 2*	*Group 3*	*All*
No Enrolled				
[comparison studies] No randomised/allocated				
No received intervention				
[RCTs] No of Post randomisation exclusions				
No Analysed				
No Lost to follow-up/withdrawn				
No Age: Mean *Median* *SD* *Range* **No <50** **No 50 and over**				
Hormone Receptor Status **No ER +** **No ER –** **No PR +** **No PR –**				

No HER2 + **No HER2 –**				
NPI Status **No Low Risk (NPI<3.4)** **No Medium Risk (NPI 3.4–5.4)** **No High Risk (NPI>5.4)**				
Genetic Status				
No Depcat Score: **1** **2** **3** **4** **5** **6** **7** Please record other socio-economic factors in additional patient information				
Primary Treatment: **No received primary breast conserving surgery (WLE)**				
No received primary mastectomy				
No reconstructed breast				
Primary Tumour Characteristics: **No DCIS** **No LCIS** **No Invasive** **Grade 1** **Grade 2** **Grade 3** **Size** **No Lymph Node Status +** **No Lymph Node Status –**				
Nos receiving treatment for primary breast cancer **Neoadjuvant radiotherapy** **Neoadjuvant chemotherapy** **Adjuvant radiotherapy** **Adjuvant chemotherapy** **Adjuvant tamoxifen /Endocrine** **Oopherectomy or ovarian ablation**				

Primary tumour excision margins: **No clear margins** **No unclear margins**				
Additional patient information:				

Intervention Group – Group 1

Components of the Intervention

Component 1

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the intervention? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the intervention (or component 1 of the intervention) initiated?

Frequency of the intervention:

Duration of the intervention:

Components of the Intervention

Component 2

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the intervention? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the intervention (or component 2 of the intervention) initiated?

Frequency of the intervention:

Duration of the intervention:

Components of the Intervention

Component 3

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the intervention? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the intervention (or component 3 of the intervention) initiated?

Frequency of the intervention:

Duration of the intervention:

Please use a separate sheet for any additional Group 1 intervention components.

Comparison Group – Group 2

Components of the Comparator

Component 1

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Comparator Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the comparator? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 1 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Components of the Comparator

Component 2

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the intervention? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 2 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Components of the Comparator

Component 3

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the comparator? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 3 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Please use a separate sheet for any additional Group2 comparator components.

Comparison Group – Group 3

Components of the Comparator

Component 1

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Comparator Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the comparator? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 1 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Components of the Comparator

Component 2

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the intervention? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 2 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Components of the Comparator

Component 3

- ☐ **Surveillance Mammography**
- ☐ **Unstructured Primary Care Follow Up**
- ☐ **Structured Primary Care Follow Up**
- ☐ **Specialist led Clinical Exam**
- ☐ **Healthcare Professional directed self-exam**
- ☐ **Alternative surveillance regimen** (please state)

Intervention Setting

- ☐ **Secondary Care**
- ☐ **Primary Care**
- ☐ **Other** (please state)

Who administered the comparator? (please give experience level if recorded)

- ☐ **Radiologist**
- ☐ **Hospital Clinician**
- ☐ **Breast Care Nurse**
- ☐ **Patient**
- ☐ **Other** (please state)

How long after primary treatment/at what time point was the comparator (or component 3 of the comparator) initiated?

Frequency of the comparator:

Duration of the comparator:

Please use a separate sheet for any additional intervention components.

Outcome(s) reported and time point(s)

How were outcome data collected/measured?

Did the analysis adjust for any confounding factors (if yes please state the confounding factor(s)?

How was the confounding factor categorised? (e.g. Age, <50 or 50>)

Outcome	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
Hazard Ratio (as reported by publication)					
Median Time to Event					
No. Overall Survival					
Alive					
Dead					
No. Disease free survival (without IBTR)					
Nos with IBTR					

No. Disease free survival (without MCBC) **Nos with MCBC** **No. Attending/ Uptake of mammography**					

Quality of life

Measure used	*Group 1*	*Group 2*	*Group 3*	*Notes*

Adverse events

General information on adverse events:

No. Adverse events reported & Type of Event	*Group 1*	*Group 2*	*Group 3*	*All*

Additional study information:

HTA Mammography Surveillance – Clinical Effectiveness Review 1
Data Extraction Form for Outcomes by Subgroup

Version 2 **09 December 08**

Study ID **Extractor's Initials** **Date**

List of possible subgroups:

Grade of primary breast cancer tumour, Size of primary breast cancer tumour, Lymphovascular Invasion, NPI status, ER/PR/HER2 status, Genetic status (BRCA genes), *Age* (Under 50 years, 50 years and over), *Type and extent of surgery for primary breast cancer tumour (*Breast conserving, Mastectomy, Excision margins), *Primary neoadjuvant / adjuvant treatment (*Radiotherapy, Chemotherapy, Tamoxifen/Endocrine treatment, Oopherectomy or ovarian ablation) Depcat status

Outcome	**Subgroup** Please write below.	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
Hazard Ratio (as reported by publication)						
Median Time to Event						

Outcome	**Subgroup** Please write below.	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
No. Overall Survival **Nos Alive** **Nos Dead**						

Outcome	**Subgroup** Please write below.	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
<u>No. Disease free survival</u> **Nos without IBTR** **Nos with IBTR**						

Outcome	**Subgroup** Please write below.	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
Nos without MCBC						
Nos with MCBC						

Outcome	**Subgroup** Please write below.	**Time Reported** Please record for all reported time points e.g. Year 1, year 2, year 3, etc.	**Group 1**	**Group 2**	**Group 3**	*All*
No Attending/ Uptake of mammography						
Quality of Life (state Measure used)						
Adverse Events (give details)						