

## Understanding the impact of cancer diagnosis and treatment on everyday life

### 36 MONTH BREAST CANCER CRF

*FOR STAFF USE ONLY*

#### CRF Completion Instructions

- Please complete as much of the CRF as possible
- **Please refer to your copies of previous CRFs when completing this 36 month CRF: please complete any additional treatment details that were not captured at 24 months (for example, additional treatments, or end dates of those ongoing in earlier CRFs)**
- If you have any queries, please contact the HORIZONS Co-ordinating Centre, email address [HORIZONS@soton.ac.uk](mailto:HORIZONS@soton.ac.uk)
- Please tick boxes when appropriate
- When you have completed the CRF, please keep a copy for your own records and return a copy to us, by post, fax or email along with the completed return cover sheet

Participant's Study ID   /   /

Participant's date of birth     /   /

Has the participant developed any NEW co-morbidities (which were not recorded in any previous CRFs)? (please tick all that apply in the tables below and overleaf)

|  |  |
|--|--|
| Myocardial infarct   |  |
| Angina/coronary artery disease   |  |
| Congestive Heart Failure   |  |
| Cardiac Arrhythmias  |  |
| Hypertension   |  |
| Venous Disease (PE/DVT)  |  |
| Peripheral Arterial Disease  |  |
| Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, asthma etc.)                                      |  |
| Liver Disease (portal hypertension, chronic/acute hepatitis, cirrhosis etc.)                                       |  |
| Stomach Ulcers or Inflammatory Bowel Disease   |  |
| Acute or Chronic Pancreatitis  |  |
| End-stage Renal Disease (chronic renal insufficiency, dialysis etc.)   |  |
| Thyroid problems (hyperthyroidism, hypothyroidism etc.)  |  |
| Diabetes Mellitus Type 1   |  |
| Diabetes Mellitus Type 2   |  |
| Stroke/TIA   |  |
| Dementia   |  |
| Paralysis (paraplegia or hemiplegia)   |  |
| Neuromuscular Condition (multiple sclerosis, Parkinson's, myasthenia gravis, other chronic neuromuscular disorder) |  |
| Clinical diagnosis of anxiety  |  |
| Clinical diagnosis of depression   |  |
| Other Psychiatric Diagnosis (eg. schizophrenia, bipolar disorder etc.)   |  |

Participant's Study ID   /   /

|  |  |
|--|--|
| Osteoarthritis   |  |
| Rheumatoid Arthritis   |  |
| Other Rheumatological Disease (systemic lupus, mixed connective tissue disorder, polymyositis, rheumatic polymyositis, scleroderma etc.) |  |
| HIV/AIDS   |  |
| Alcohol Abuse (or history of, must be accompanied by social, behavioural or medical complications)                                       |  |
| Drug/Substance Abuse (or history of, must be accompanied by social, behavioural or medical complications)                                |  |
| Morbid Obesity   |  |
| Other (please give details) _____  |  |
| Other (please give details) _____  |  |
| Other (please give details) _____  |  |

Participant's Study ID   /   /

What treatments has the participant received **since those captured in any previous CRFs**, please tick ALL that apply and write details in the spaces provided. Please add end dates for any treatments which were ongoing previously (table continued overleaf).

| Treatment type               | Specific treatment details                                      | Tick if patient has received | Date of surgery or start date of other treatment (dd/mm/yyyy) | End date of treatment (if finished) (dd/mm/yyyy) | If course of treatment was not completed as planned, please give a reason why |
|------------------------------|---|------------------------------|---|--|---|
| <b>Surgery</b>               | Wide local excision (breast conserving surgery)                 |                              | __ / __ / 20__  |  |   |
|                              | Mastectomy  |                              | __ / __ / 20__  |  |   |
|                              | Sentinel node biopsy (SNBx)                                     |                              | __ / __ / 20__  |  |   |
|                              | Axillary node clearance (ANC)                                   |                              | __ / __ / 20__  |  |   |
|                              | Other axillary treatment please describe on line below<br>_____ |                              | __ / __ / 20__  |  |   |
| <b>Breast Reconstruction</b> | Immediate reconstruction  |                              | __ / __ / 20__  |  |   |
|                              | Delayed reconstruction  |                              | __ / __ / 20__  |  |   |
|                              | Delayed reconstruction is planned but has not yet taken place   |                              |   |  |   |
| <b>Reconstruction Type</b>   | Implant   |                              | __ / __ / 20__  |  |   |
|                              | Latissimus dorsi (LAD)  |                              | __ / __ / 20__  |  |   |
|                              | Deep inferior epigastric perforator artery (DIEP)               |                              | __ / __ / 20__  |  |   |
|                              | Tissue reconstruction with abdominal tissue (TRAM)              |                              | __ / __ / 20__  |  |   |
|                              | Nipple reconstruction   |                              | __ / __ / 20__  |  |   |
|                              | Nipple/Areola Tattoo  |                              | __ / __ / 20__  |  |   |
|                              | Other (please describe on line below)<br>_____                  |                              | __ / __ / 20__  |  |   |

Participant's Study ID   /   /

| Treatment type   | Specific treatment details                                   | Tick if patient has received | Date of surgery or start date of other treatment (dd/mm/yyyy) | End date of treatment (if finished) (dd/mm/yyyy) | If course of treatment was not completed as planned, please give a reason why |
|--|--|------------------------------|---|--|---|
| <b>Radiotherapy</b>  | Breast   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Chest wall   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Supraclavicular fossa (SCF)                                  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Axilla   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Number of radiotherapy fractions, please enter on line _____ |                              |   |  |   |
| Total radiotherapy dose please enter on line _____                         |  |                              |   |  |   |
| <b>Chemotherapy</b>  | Drug(s), please give details<br>_____                        |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Chemotherapy number of cycles, please enter on line _____    |                              |   |  |   |
| <b>Ovarian Suppression</b>   | Medical, please give details below<br>_____                  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Surgical   |                              | __ / __ / 20__  |  |   |
|  | Radiotherapy   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
| <b>Hormone Therapy</b>   | Tamoxifen  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Anastrozole  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Letrozole  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Exemestane   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|  | Other, please give details<br>_____                          |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
| Were bisphosphonates given (please tick)?<br>Yes ____ No ____ Unknown ____ |  |                              |   |  |   |

Participant's Study ID   /   /

| Treatment type                   | Specific treatment details  | Tick if patient has received | Date of surgery or start date of other treatment (dd/mm/yyyy) | End date of treatment (if finished) (dd/mm/yyyy) | If course of treatment was not completed as planned, please give a reason why |
|----------------------------------|---|------------------------------|---|--|---|
| <b>Symmetrisation Operations</b> | Contralateral risk reducing mastectomy                              |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|                                  | Other symmetrisation operation (please give details)<br>_____       |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|                                  | Other risk reducing surgery (please give details)<br>_____          |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
| <b>Immunotherapy</b>             | Trastuzumab (Herceptin)   |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|                                  | Pertuzumab (Perjeta)  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
|                                  | Other immunotherapy (please give details)<br>_____                  |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |
| <b>Additional Treatment</b>      | If any additional treatment has been given please describe<br>_____ |                              | __ / __ / 20__  | __ / __ / 20__                                   |   |

Were any of the treatments detailed above given with **palliative intent**? (please tick one box)

Yes

No

Unknown

If yes, please indicate which treatments?

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Participant's Study ID  /  /

Has the participant had a **local** recurrence of their breast cancer? (please tick one box)

|     |                          |    |                          |         |                          |
|-----|--------------------------|----|--------------------------|---------|--------------------------|
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | Unknown | <input type="checkbox"/> |
|-----|--------------------------|----|--------------------------|---------|--------------------------|

If the participant has had a **local** recurrence, on what date was the recurrence diagnosed?

|   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|
| d | d | m | m | y | y | y | y |
|---|---|---|---|---|---|---|---|

Since the participant's diagnosis of breast cancer, has there been any evidence of distant metastatic disease? (please tick one box)

|     |                          |    |                          |         |                          |
|-----|--------------------------|----|--------------------------|---------|--------------------------|
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | Unknown | <input type="checkbox"/> |
|-----|--------------------------|----|--------------------------|---------|--------------------------|

If you have answered "yes" to the above question, on what date was the metastatic disease diagnosed:

|   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|
| d | d | m | m | y | y | y | y |
|---|---|---|---|---|---|---|---|

Please provide details of the site(s) of distant metastatic disease:

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Is the participant pre or post menopause? (please tick one box)

|                |                          |
|----------------|--------------------------|
| Pre menopause  | <input type="checkbox"/> |
| Post menopause | <input type="checkbox"/> |
| Unknown        | <input type="checkbox"/> |

Participant's Study ID   /   /

Is the participant taking part in a clinical trial? (please tick one box)

|     |                          |    |                          |         |                          |
|-----|--------------------------|----|--------------------------|---------|--------------------------|
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | Unknown | <input type="checkbox"/> |
|-----|--------------------------|----|--------------------------|---------|--------------------------|

If you answered "yes" to the above question, please give the NAME of the clinical trial the participant is taking part in

Name of clinical trial \_\_\_\_\_

Since the participant's diagnosis of breast cancer, have they been diagnosed with another new primary cancer? (please tick one box)

|     |                          |    |                          |         |                          |
|-----|--------------------------|----|--------------------------|---------|--------------------------|
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | Unknown | <input type="checkbox"/> |
|-----|--------------------------|----|--------------------------|---------|--------------------------|

If you answered "yes" to the above question, please provide some information about the participant's new cancer diagnosis by completing the table below

|                                    |                |
|------------------------------------|----------------|
| Type of cancer                     |                |
| Date of diagnosis                  | __ / __ / 20__ |
| Treatment received                 |                |
| Date treatment ended (if finished) | __ / __ / 20__ |

What type of follow-up care is the participant receiving? (please tick ONE box)

|  |   |
|--|---|
| Routine/regular hospital clinic based follow-up (medical or nurse led, face-to-face or by telephone)                                       | <input type="checkbox"/>  |
| Primary care based follow-up   | <input type="checkbox"/>  |
| Patient initiated follow-up (also known as patient triggered follow-up (PTFU), open access follow-up, or supported self-managed follow-up) | <input type="checkbox"/>  |
| If the participant is receiving patient-initiated follow-up, on what date were they discharged to this?                                    | <input type="checkbox"/> |

Participant's Study ID  /  /

Has the participant been referred to any of the following services and/or had a Holistic Needs Assessment? (please tick all that apply)

|   |  |
|---|--|
| Participant has been referred to palliative care services<br>If available, please give reason for referral (e.g. end of life care, symptom management)        |  |
| Participant has been referred to psychological services<br>If ticked, please provide route to referral (e.g. GP, Improving Access to Psychological Therapies) |  |
| Participant has been referred to community services   |  |
| Participant has been referred for treatment related problems (e.g. pain clinic)<br>If ticked, please provide more details below:                              |  |
| Participant has had an HNA (holistic needs assessment)  |  |
| Participant has been referred to fertility services   |  |

If the participant has died please give the date and cause of death:

Participant's date of death  /  /

Cause of participant's death

|       |  |
|-------|--|
| 1) a) |  |
| 1) b) |  |
| 1) c) |  |
| 2)    |  |

Cause of death not known

Please add your name and signature and the date that you completed this CRF

Name \_\_\_\_\_ Signature \_\_\_\_\_

Date CRF completed  /  /