SUMMARY ELIGIBILITY CRITERIA

optima
personalised treatment of breast cancer

INCLUSION CRITERIA

- Female or male, age ≥ 40
- Excised invasive breast cancer with local treatment either completed or planned according to trial guidelines.
- ER positive AND HER2 negative
- Tumour size and axillary lymph node status; one of the following must apply:
  i. 4-9 lymph nodes involved AND with any invasive tumour size.
  ii. 1-3 nodes involved, at least 1 node containing a macrometastasis (i.e. deposit >2mm diameter) AND with any invasive tumour size.
  iii. 1-3 lymph nodes involved with micrometastases only (i.e. deposit >0.2-2mm diameter) AND invasive tumour size ≥ 20mm.
  iv. node negative AND invasive tumour size ≥ 30mm.
- Considered appropriate for adjuvant chemotherapy by treating physician.
- Patient must be fit to receive chemotherapy and other trial-specified treatments with no concomitant medical, psychiatric or social problems that might interfere with informed consent, treatment compliance or follow up.
- Bilateral cancers are permitted provided at least one tumour fulfils the entry criteria and the contralateral tumour is ER positive and HER2 negative **but not** clinically significant.
  Refer to full eligibility criteria for definition of clinical significance.
- Multiple ipsilateral cancers are permitted provided at least one tumour fulfils the entry criteria and none meet any of the exclusion criteria.
- Short term pre-surgical treatment with endocrine therapy including in combination with non-cytotoxic investigational agents is allowed providing that the duration of treatment does not exceed 8 weeks.
  NOTE: A pre-treatment core biopsy should be sent to the Central Laboratory; a sample from a surgical excision or other on-treatment biopsy is not acceptable.
- Written informed consent for the study.

EXCLUSION CRITERIA

- ≥10 involved axillary nodes (macrometastases and/ or micrometastases) or evidence of internal mammary node involvement.
- ER negative OR HER2 positive/amplified (determined by the referring site).
- Metastatic disease.
- Previous diagnosis of malignancy unless:
  i. managed only by surgical treatment with or without local radiotherapy AND disease-free for 10 years
  ii. basal cell carcinoma of skin or cervical intraepithelial neoplasia
  iii. ductal carcinoma in situ (DCIS) or pleomorphic lobular carcinoma in situ (pleomorphic LCIS) treated with surgery with or without breast radiotherapy; treatment with anti-oestrogens is not permitted.
- Use of systemic anti-cancer treatment and/or radiotherapy for breast cancer prior to trial entry except as follows.
  i. Short-term pre-surgical endocrine therapy as per the inclusion criteria.
  ii. Endocrine therapy administered following surgery provided this is discontinued at trial entry.
- Treatment with agents, including ovarian suppression, known to influence breast cancer growth but prescribed for other indications within one year of trial entry except as follows.
  i. Use of oestrogen replacement therapy (HRT) provided this is stopped before surgery.
  ii. Drugs administered for in vitro fertilization or fertility preservation.
  iii. Use of hormonal contraception.
- Trial entry and randomisation more than 12 weeks after completion of breast cancer surgery.
- Planned further surgery for breast cancer, including axillary surgery, to take place after randomisation, except either re-excision or completion mastectomy for close/involved margins which may be undertaken following completion of chemotherapy. *Timing of axillary radiotherapy is unrestricted.*

Please check the full eligibility criteria in protocol v6 to ensure potential participants meet these before consenting into the study.