Randomisation Form for International Sites

optima personalised treatment of breast cancer

Version 4.0 — 25 Jan 2021

Form #2(i)

Participant Trial Number: ☐☐☐☐

To randomise, please enter the below details onto the online Randomisation system

2.1 SITE DETAILS *(Refer to completion guidance for this section)*

Country:

Site:

Randomising investigator: (individual who obtained consent)

2.2 CONTACT'S DETAILS *(Refer to completion guidance for this section)*

Name:

Telephone:

Fax:

2.3 PARTICIPANT DETAILS *(Refer to completion guidance for this section)*

1. Participant initials: ☐☐☐

2. Gender: Female ☐ Male ☐

3. Date of birth: ☐☐ - ☐☐☐ - ☐☐☐☐ (d d - m m m - y y y y)

4. Has the patient been treated with pre-surgical endocrine therapy? Yes ☐ No ☐

*If **YES** a pre-treatment core biopsy must be sent to the Central Laboratory.*

2.4 STRATIFICATION (please select one answer for each question)

For questions 1 to 3: If the participant has multiple tumours, please see form completion guidance on page 3 for information on which tumour the patient should be stratified by.

1. Invasive tumour size: < 30mm ☐ ≥ 30mm ☐

2. Histological grade: Grade 1 ☐ Grade 2 ☐ Grade 3 ☐

3. Number of involved nodes:

- Node negative (includes Isolated Tumour Cells only) ..... ☐
- Positive sentinel node biopsy with micrometastases only and no axillary clearance ..... ☐
- Positive sentinel node biopsy with macrometastases and no axillary clearance ..... ☐
- 1-3 involved nodes with axillary clearance (count both micrometastases and macrometastases) ... ☐
- 4-9 involved nodes with axillary clearance (count both micrometastases and macrometastases) ... ☐

4. Intended chemotherapy regimen:

FEC75-80 ☐ E-CMF ☐ (F)EC-T ☐ (F)EC-Pw/P2w ☐ dd AC/EC-P ☐

FEC90-100 ☐ EC90-100 ☐ TC ☐ TAC ☐

5. Menopausal status:

Male ☐

Postmenopausal ☐

Premenopausal ☐ → **If premenopausal, state intended endocrine therapy:**

Tamoxifen + ovarian suppression ☐

Aromatase inhibitor + ovarian suppression ☐

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2.5 PARTICIPANT ELIGIBILITY (answers must fall in unshaded boxes)

	No	Yes
1. Has a designated individual completed and signed an Eligibility Form? *(Refer to completion guidance)*	☐	☐
2. Does the participant meet all of the eligibility criteria?	☐	☐

2.6 PARTICIPANT CONSENT FOR OPTIMA (answers must fall in unshaded boxes)

	No	Yes
1. Has the participant given informed consent to be randomised?	☐	☐

2. Please confirm type of consent received prior to randomisation:

☐ Full written consent

Have all the fields on the consent form been completed correctly?	☐	☐
Has the participant consented to share their anonymised data for future studies?	☐	☐
Has the participant consented to donate their tumour sample to future research?	☐	☐
Has the participant consented to be contacted regarding future studies?	☐	☐

Date consent form signed by participant: ☐☐-☐☐☐-☐☐☐☐ (d d - m m m - y y y y)

OR ☐ Remote Verbal consent*

(*Remember to complete CRF2a once written consent is completed)

Date of Remote Verbal Consent: ☐☐-☐☐☐-☐☐☐☐ (d d - m m m - y y y y)

Form completed by

Printed name: _____

Signature: _____

Date signed: ☐☐-☐☐☐-☐☐☐☐ (d d - m m m - y y y y)

N.B. The individual named must be on the delegation log with the assigned responsibility to perform randomisation.

TO BE COMPLETED BY SITE AFTER RANDOMISATION

(please also record the Participant Trial Number in the form header on Page 1)

PARTICIPANT TRIAL NUMBER: ☐☐☐☐

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Completion Guidelines for CRF 2 - Randomisation Form

2.1. SITE DETAILS

Randomising investigator

This is the trial investigator who counter-signed the participant's consent form. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to obtain informed consent.

2.2. CONTACT'S DETAILS

Contact's name

This will be the person the randomisation confirmation fax and email will be sent to and to whom queries regarding the randomisation will be directed. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to perform randomisation.

2.3. PARTICIPANT DETAILS

Participant initials

Write the initials of the participant's first/given name, middle name and surname/family name. If no middle name place dash ("-") in middle box.

Date of birth: Please use the following format for dates: 06-Jun-1956.

Has the patient been treated with pre-surgical endocrine therapy?

If yes, a pre-treatment core biopsy **must** be sent to the Central Laboratory for processing; a sample from a surgical excision or other on-treatment biopsy is not acceptable. Refer to the Protocol / Site Sample Collection SOP for further guidance.

2.4. STRATIFICATION

Questions 1 to 3

If the participant has multiple ipsilateral tumours which meet the inclusion criteria please record details of the tumour with the highest Nottingham Prognostic Index (NPI) score. NPI score is calculated using the following formula:

NPI Score = (0.2 x Invasive tumour size) + Grade + Nodal status

Where:

- Invasive tumour size (*not total tumour size*) is measured in cm
- Grade is the histological grade: Grade 1 = Score 1 | Grade 2 = Score 2 | Grade 3 = Score 3
- Nodal status: No positive nodes = Score 1 | 1-3 positive nodes = Score 2 | ≥4 positive nodes = Score 3

The number of nodes is the total from all surgical procedures and includes both micro– and macro-metastasis.

Examples:

For a 30mm Grade 2 carcinoma with 2 nodes positive the NPI = 4.6 (Derived from [0.2 x 3.0] + 2 + 2)

For an 8mm Grade 3 carcinoma with 2 nodes positive the NPI = 5.16 (Derived from [0.2 x 0.8] + 3 + 2)

Record the details of the 8mm Grade 3 carcinoma as this has the higher score.

In practice, for comparing tumours nodal status can be ignored, as this is the same for all tumours in the breast.

Menopausal status

Women who fulfil the following criteria at trial entry will be considered postmenopausal:

- Age >45 and natural amenorrhoea of at least 1 year's duration
- Bilateral surgical oophorectomy
- For amenorrhoea not fulfilling the above criteria the diagnosis of postmenopausal status should be supported by hormone measurement: FSH levels must be > 25IU/L with low oestradiol (i.e. within the locally defined postmenopausal range), in the event of doubt measured on 2 occasions preferably 4-6 weeks apart. This applies to women who have undergone hysterectomy without bilateral surgical oophorectomy and are age <60; those ≥60 may be considered postmenopausal. Women who do not fulfil the above criteria (and those who develop post-chemotherapy amenorrhoea) should be considered to be premenopausal.

Please note: hormonal contraception will suppress FSH and oestradiol levels. In those taking oral contraception, levels will recover rapidly on discontinuation. Depo-Provera injectable contraception lasts many months: all such women should be considered premenopausal.