Neo-tAnGo Paper Randomisation Form

Caller's name *(please print)*: | **Caller's contact numbers:** ☎: | **Fax:**

Has the patient given permission for her full name to be collected?

No ☐ ➡ **Patient's initials:** ☐☐
FIRST and LAST initials only

Yes ☐ ➡ **First Name:** | **Surname:**

Date of Birth.: *dd* *mon* *yyyy*

Hospital no.: | **NHS or CHI no.:**

Randomising hospital:

Randomising consultant:

Hospital where EC will be administered:
(if different from randomising hospital)

Hospital where T±G will be administered:
(if different from randomising hospital)

Hospital where tumour biopsy Stored:
(if different from randomising hospital)

Patient eligibility *(all 'Yes' boxes must be ticked for patient to be eligible)*

	No	Yes
• Has the randomising consultant completed an eligibility form for this patient?	☐	☐
• Does the patient meet all of the eligibility criteria?	☐	☐
• Please confirm sufficient paraffin-embedded tumour tissue is available for the ***Neo-tAnGo*-SCIENCE** sub-study.	☐	☐

dd *mon* *yyyy*

Date of diagnostic biopsy (must be no more than 4 weeks ago):

Chemotherapy start date (must be within 4 weeks of diagnostic biopsy date):

Essential information required at randomisation

ER status: Negative ☐ Positive ☐

Tumour size: ≤ 50 mm ☐ > 50 mm ☐

			Liver biochemistry		Bone biochemistry	
Clinical involvement of axillary nodes:	No ☐	Yes ☐ *If 'Yes'* →	≤2×ULN ☐	>2×ULN ☐	≤2×ULN ☐	>2×ULN ☐
Inflammatory/ locally advanced disease:	No ☐	Yes ☐ *If 'Yes'* →	≤2×ULN ☐	>2×ULN ☐	≤2×ULN ☐	>2×ULN ☐
Abnormal full blood count:	No ☐	Yes ☐ *If 'Yes'* →	≤2×ULN ☐	>2×ULN ☐	≤2×ULN ☐	>2×ULN ☐

See Eligibility Form for mandatory screening investigations and timings.

If 'Yes': Liver Scan results required[1] | If 'Yes': Bone Scan results required[2]

Abnormal liver biochemistry[1]: No ☐ Yes ☐ *If 'Yes'* → **Liver scan:** Normal ☐ Abnormal ☐

Abnormal bone biochemistry[2]: No ☐ Yes ☐ *If 'Yes'* → **Bone scan:** Normal ☐ Abnormal ☐

Patient's weight: ☐☐☐.☐ **kg** **Patient's height:** ☐.☐☐ **m**

OPTIONAL patient consent issues

	No	Yes
• Does the patient wish to receive a summary of the ***Neo-tAnGo*** trial results when they are published?	☐	☐
• Has the patient agreed to collection of **fresh** tumour tissue for **CTCR-BR01** sub-study?	☐	☐
• Does the patient wish to be informed of any findings from genetic research which may affect family members?	☐	☐
• Does the patient wish to participate in the Quality of Life sub-study? (If *'Yes'*, give address on reverse of form)	☐	☐
• If, *'Yes'* to Quality of Life, has the patient already completed her baseline questionnaire? (Collect address)	☐	☐

Treatment allocation

Arm A1: EC→Taxol ☐ **Arm A2:** Taxol→EC ☐ **Arm B1:** EC→Taxol + Gemzar ☐ **Arm B2:** Taxol + Gemzar→EC ☐

Inform the caller that due to technical difficulties, you are unable to allocate a trial number at present. They will be informed of the patient's trial number in the Randomisation Confirmation letter, or sooner by telephone if they prefer. ***Tick here if notification by phone requested:*** ☐

TNO: ☐☐☐

Signed: _____ **Time:** ___ : ____ **Date:** *dd* *mon* *yyyy*

Patient's address details for Quality of Life sub-study:

Address 1: _____

Address 2: _____

_____

Town: _____

County: _____

Postcode: _____