Appendix

Data Collection Form

Patient Code:			Patient Initials: _ _ _		
Age at diagnosis:	Date of diagnosis (yyyy):	ER: ❒ + ❒ -	PR: ❒ + ❒ -	Her2: ❒ + ❒ -	Ki67: ❒ + ___% ❒ -
Diagnosis (with Stage) and histology:					
Histologic grade: ❒ 1 ❒ 2 ❒ 3	Nuclear grade: ❒ 1 ❒ 2 ❒ 3	Lymphovascular Invasion: ❒ Yes ❒ No		Menopause: ❒ Yes ❒ No	

Neoadjuvant Treatment:

❒ Endocrine_____

❒ Cytotoxic_____

❒ Anti-Her2_____

❒ Combination_____

Adjuvant Treatment:

❒ Cytotoxic chemotherapy only _____

❒ Endocrine therapy only _____

❒ Radiotherapy only _____

❒ Cytotoxic + anti-Her 2 _____

❒ Cytotoxic followed by Endocrine therapy and RT _____

❒ Cytotoxic followed by Endocrine therapy_____

❒ Cytotoxic + anti-Her 2 followed by endocrine therapy _____

❒ Endocrine therapy + RT _____

❒ Cytotoxic + anti-Her 2 and endocrine therapy with RT _____

Surgery:	Outcomes
❒ Breast Conservation Surgery	❒ Alive ❒ Complete response
❒ Modified radical mastectomy	❒ Alive with disease ❒ Partial response
❒ Axillary Lymph Node Dissection	❒ Dead from any cause ❒ Stable disease
	Date of disease recurrence (yyyy):
	Date of death (yyyy):
	Date last seen alive (yyyy):

Completed by: _____

Name Signature Date

RECIST VERSION 1.1

At baseline, tumour lesions/lymph nodes will be categorised measurable or non-measurable as follows:

1. Measurable
   Tumour lesions: Must be accurately measured in at least one dimension (longest diameter in the plane of measurement is to be recorded) with a minimum size of:

   - 10 mm by CT scan (CT scan slice thickness no greater than 5 mm; see Appendix II on imaging guidance).
   - 10 mm caliper measurement by clinical exam (lesions which cannot be accurately measured with calipers should be recorded as non-measurable).
   - 20 mm by chest X-ray.

Malignant lymph nodes: To be considered pathologically enlarged and measurable, a lymph node must be P15 mm in short axis when assessed by CT scan (CT scan slice thickness recommended to be no greater than 5 mm). At baseline and in follow-up, only the short axis will be measured and followed .

2. Non-measurable

All other lesions, including small lesions (longest diameter <10 mm or pathological lymph nodes with P10 to <15 mm short axis) as well as truly non-measurable lesions. Lesions considered truly non-measurable include: leptomeningeal dis- ease, ascites, pleural or pericardial effusion, inflammatory breast disease, lymphangitic involvement of skin or lung, abdominal masses/abdominal organomegaly identified by physical exam that is not measurable by reproducible imaging techniques.

3. Evaluation of target lesions

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.

Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).

Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study

4. Evaluation of non-target lesions

This section provides the definitions of the criteria used to deter- mine the tumour response for the group of non-target lesions. While some non-target lesions may actually be measurable, they need not be measured and instead should be assessed only qualitatively at the time points specified in the protocol.

Complete Response (CR): Disappearance of all non-target lesions and normalisation of tumour marker level. All lymph nodes must be non-pathological in size (<10 mm short axis).

Non-CR/Non-PD: Persistence of one or more non-target lesion(s) and/or maintenance of tumour marker level above the normal limits.

Progressive Disease (PD): Unequivocal progression (see comments below) of existing non-target lesions. (Note: the appearance of one or more new lesions is also considered progression).