NCI BOLD Task Force
Common Data Elements (CDE) - Pre-Operative Systemic Therapy

Patient ID: --------------------------------------

**CLINICAL Evaluation of Breast and Lymph Nodes**

Time Point: □ Before preoperative systemic therapy
□ During preoperative systemic therapy
□ At completion of planned preoperative systemic therapy

*Note:* If evaluations were done at more than one time point during pre-operative chemotherapy, please complete a pre-operative CDE for each of those time points.

Cycle Number _____ Date of Evaluation __ __/__ __/ __ __ __ __

**Primary Tumor**
Neoadjuvant Clinical T stage
□ ycTX □ ycT0 □ ycT1 □ ycT1a □ ycT1b □ ycT1c □ ycT2 □ ycT3
□ ycT4 □ ycT4a □ ycT4b □ ycT4c □ ycT4d

Note: DCIS and LCIS are NOT clinical exam findings and are addressed in pathology section

Longest Diameter of Lesion (largest tumor if multifocal or multicentric disease) __ __ __ . __ __cm

Does the patient have bilateral malignancy (including DCIS)? □ Yes □ No

**Nodal Disease**
Neoadjuvant Clinical N Stage □ ycNX □ ycN0 □ ycN1 □ ycN2 □ ycN3

**Imaging Examination of Breast and Lymph Nodes**

Time Point: □ Before preoperative systemic therapy
□ During preoperative systemic therapy
□ At completion of planned preoperative systemic therapy

Cycle Number _____ Date of Evaluation __ __/__ __/ __ __ __ __

Please complete Imaging Module 1 for each assessment done during pre-operative therapy.

Was a clip placed prior to initiation of pre-operative therapy to mark:
Primary tumor □ Yes □ No
Positive axillary node □ Yes □ No

Was a specimen radiograph obtained at the time of definitive surgery? □ Yes □ No

Is the clip visible on the specimen radiograph?
Primary tumor □ Yes □ No
Axillary node □ Yes □ No
PATHOLOGIC (Post-Treatment) Evaluation of Breast and Lymph Nodes

Number of residual primary tumors (multifocality defined as tumors or fibrous tumor beds that are separated by more than 2 cm of intervening normal breast tissue)

☐ 0    ☐ 1    ☐ 2    ☐ 3    ☐ >3

Comment:

Largest diameter of residual invasive cancer (for T Stage) __________ mm

Histologic Type
☐ Invasive (infiltrating) ductal carcinoma
☐ Invasive (infiltrating) lobular carcinoma
☐ Invasive mixed ductal and lobular carcinoma
☐ Invasive mammary carcinoma (not otherwise specified)
☐ Other (please specify) __________________________

Pathologic T Stage
☐ ypT0    ☐ ypT0is    ☐ ypT1mic    ☐ ypT1a    ☐ ypT1b    ☐ ypT1c
☐ ypT2    (Post Neoadjuvant)    ☐ ypT3    ☐ ypT4    ☐ ypT4a    ☐ ypT4b    ☐ ypT4c    ☐ ypT4d
☐ ypTX

Pathologic N Stage
☐ ypN0    ☐ ypN0(i+), ☐ ypN0(i-)    ☐ ypN0(mol+)    ☐ ypN0(mol-)    ☐ ypN1
☐ ypN1a    ☐ ypN1b    ☐ ypN1c    ☐ ypN1mic    ☐ ypN2    ☐ ypN2a
☐ ypN2b    ☐ ypN3    ☐ ypN3a    ☐ ypN3b    ☐ ypN3c    ☐ ypNX

Tumor infiltrating lymphocytes:    ☐ None/minimal    ☐ Present    ☐ Extensive    ☐ Unknown/Not reported

Does analysis of the tissue show therapeutic effects from preoperative therapy? ☐ Yes    ☐ No

If yes, were therapeutic changes noted in ☐ breast only    ☐ nodes only    ☐ breast and nodes

Evidence of therapeutic effects?
☐ Histiocytoid    ☐ Cytoplasmic vacuolization
☐ Apocrine/Eosinophilic    ☐ Lobular appearance
☐ Other, specify________________________    ☐ No

Pathologic status of surgical margins (See Surgical CDE)

RESIDUAL CANCER BURDEN IN THE BREAST

Primary Tumor Bed Area __. __ mm X __. __ mm

NOTE: The tumor bed is defined from the review of both macroscopic and microscopic findings

NOTE: If there are multifocal residual tumor beds, then report the largest

Overall cancer cellularity (%)
☐ 0%    ☐ 5%    ☐ 10%    ☐ 20%    ☐ 30%    ☐ 40%    ☐ 50%    ☐ 60%    ☐ 70%    ☐ 80%    ☐ 90%
☐ other %

NOTE: Cancer cellularity is the average cellularity by area across the entire tumor bed
Percentage of residual cancer that is IN SITU disease
☐ 0%  ☐ 5%  ☐ 10%  ☐ 20%  ☐ 30%  ☐ 40%  ☐ 50%  ☐ 60%  ☐ 70%  ☐ 80%  ☐ 90%
☐ 100%  other ___%

Number of Involved Lymph Nodes ________

Size of Largest Nodal Metastasis _____ . ___ mm

Residual Cancer Burden Index __________
To be calculated from the RCB website (www.mdanderson.org/breastcancer_RCB)

Residual Cancer Burden Class  ☐ 0 (RCB Index = 0)
☐ I (RCB Index of > 0 up to less than or equal to 1.36)
☐ II (RCB Index of >1.36 up to less than or equal to 3.28)
☐ III (RCB Index of > 3.28)

Note: A detailed protocol for pathologists, examples of % cancer cellularity, explanations of tumor bed measurements, evaluation of cancer cellularity, and Residual Cancer Burden Class and Index can be found at http://www.mdanderson.org/breastcancerRCB