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
                    (Post Neoadjuvant)  □ 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