

**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](http://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>