

**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>