

**NCI BOLD Task Force
Common Data Elements (CDE) – General**

*The following represents a **SUMMARY OF ALL SURGERIES**
(as such this will require continuous updating).*

I. General patient & protocol information

Patient ID

Patient ID (protocol ID + sequentially assigned number based on order of registration) _____

Patient Characteristics at Registration

Patient age at registration (in years) _____

Note: Can be computed from Date of Birth and Date of Registration by local system.

Menopausal Status (check one)

- Pre (<6 mo since LMP AND no prior bilateral ovariectomy AND not on estrogen replacement)
- Post (prior bilateral ovariectomy OR >12 mo since LMP with no prior hysterectomy AND not currently receiving therapy with LH-RH analogs (e.g., Zoladex))
- Above categories not applicable AND Age < 50
- Above categories not applicable AND Age >= 50

Patient's Vital Status Alive Dead

Primary Cause of Death (**check one**)

- Due to this disease Due to other cause Due to protocol treatment
- Accidental Suicide Other

Describe cause of death _____

Patient Performance Status

ECOG Performance Status (**check one**)

- 0 = Fully active, able to carry on all pre-disease performance without restriction. (Karnofsky 90 - 100)
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,(e.g. light housework, office work). (K 70 - 80)
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours. (K 50 - 60)
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. (K 30 - 40)
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. (K 10 - 20)

Karnofsky Performance Status (**check one**)

- 100 = Normal, no complaints, no evidence of disease
- 90 = Able to carry on normal activity; minor signs or symptoms of disease
- 80 = Normal activity with effort; some signs or symptoms of disease
- 70 = Cares for self, unable to carry on normal activity or to do active work
- 60 = Requires occasional assistance, but is able to care for most of his/her needs
- 50 = Requires considerable assistance and frequent medical care
- 40 = Disabled, requires special care and assistance
- 30 = Severely disabled, hospitalization indicated. Death not imminent

- 20 = Very sick, hospitalization indicated. Death not imminent
- 10 = Moribund, fatal processes progressing rapidly
- 0 = Dead

Protocol Design (To be adjusted per protocol specifics)

Assigned Treatment Arm

Treatment Assignment Code Example (TAC) (protocol specific)

TAC description (Note: The following fields can be prepopulated)

Agent NSC Number*	Agent Name	Agent Dose	Unit**	Route***	Frequency****
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

* Please check the CTEP Home Page for a list of agent NSC numbers.

** Unit = mg/m², mg/kg, mg

*** Route = IM, IV, NASAL, PO, Transdermal, TOP, or Vaginal

**** Frequency = bid (Twice a Day), tid (Three Times Daily), qid (Four Times Daily), qd (Daily), q2d (Every two days), q3d (Every three days), qd x 3 (Once a day for 3 days), qd x 4 (Once a day for 4 days), qd x 5 (Once a day for 5 days), qod (Every Other Day), qam (Every Morning), qhs (Every night), PRN (As Needed), qwk (Weekly), 2 times/week, 3 times/week, Tiw (Three Times a Week), Biw (Every two weeks), q2wk (Every two weeks), qmonth (Monthly), ac (Before meals), pc (After Meals), q1h (Every one hour), q2h (Every two hours), q3h (Every three hours), q4h (Every four hours), q6h (Every six hours), q8h (Every eight hours), q12h (Every twelve hours), x1 (One Time), x2 (Two Times), x3 (Three Times), x4 (Four Times)

II. Disease Description

Initial Diagnostic Specimen (BIOPSY)

Tumor Laterality (check one) Left Right Bilateral

Method of Evaluation: Fine needle aspiration biopsy Core biopsy Incisional biopsy
 Excisional biopsy or lumpectomy Skin biopsy Excisional biopsy with frozen section

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) _____

Histologic Grade (note, this is the summary of architectural, nuclear, and mitotic count itemized below)

Low Intermediate High Unknown

Architectural grade (tubule formation), if ductal carcinoma 1 2 3

Nuclear grade Low Intermediate High *Unknown/Not reported*

Mitotic Count 1 2 3 Unknown

Lymphovascular invasion Yes No Equivocal Unknown/Not reported

Tumor infiltrating lymphocytes: None/minimal Present Extensive Unknown/not reported

IN SITU DISEASE in Biopsy

Assessment of Ductal Carcinoma In Situ (DCIS)

Is DCIS present? Yes No Unknown

Is DCIS present with invasive cancer? Yes No *Unknown*

If present with invasive disease, Is an extensive intraductal component (EIC) present? Yes No

Is cancerization of lobules present? Yes No

DCIS Histologic Type Comedo Apocrine
(check all that apply) Solid Intra-cystic (encysted papillary)
 Cribriform Papillary
 Micropapillary
 Clinging Other, specify _____

Is Paget's disease of the nipple present? Yes No Unknown

Is microinvasive cancer present? Yes No Unknown

Assessment of Lobular Carcinoma In Situ (LCIS)

Is LCIS present? Yes No

Is LCIS present with invasive cancer? Yes No

Extent of LCIS Focal Extensive Not specified

Marker Status

Estrogen Receptor (ER) Status

Negative Positive Low Positive

1+ 2+ 3+ Unknown/Not reported

If reported, % cells (+) _____ %

Attempted, but technically inadequate

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

Progesterone Receptor (PgR) Status

Negative Positive Low Positive
 1+ 2+ 3+ Unknown/Not reported
PgR % cells stained positive _____ %

Attempted, but technically inadequate

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

Her2/neu expression by immunohistochemistry

Negative 1+ 2+ 3+ Unknown/Not reported

Positive Low Positive

Attempted, but technically inadequate

If reported, % cells (+) _____ %

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

HER2 status by FISH

FISH HER2/neu chromosome 17 (HER2:cep17) Ratio _____ : _____

Amplified (HER2:cep17 ratio >2.2) Amplified (HER2 copy number >6)

Not amplified (HER2:cep17 ratio <1.8) Not amplified (HER2 copy number <4)

Equivocal (HER2:cep17 ratio 1.8-2.2) Equivocal (HER2 copy number 4-6)

Not done/Not reported

Attempted, but technically inadequate

Method/Kit Used:

Final HER2 status

Negative Positive Equivocal Not done/Not reported

Lymph Nodes

Did the patient undergo lymph node sampling prior to definitive surgery (at diagnosis)? No Yes

If yes, was there histologic or cytologic evidence of lymph node involvement?

N/A No Yes Equivocal

Date of lymph node sampling ___ / ___ / _____

Method of Evaluation: Fine needle aspiration biopsy Core biopsy Incisional biopsy Excisional biopsy or lumpectomy Sentinel node biopsy

Surgical Procedures

See Surgical CDE

Pathologic Disease Classification After Definitive Surgery *Indicate highest stage*

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) _____

Lymphovascular invasion Yes No Equivocal Unknown/Not reported

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

Pathologic status of surgical margins (see Surgical CDE)

Histologic Grade Grade I (Low) Grade II (Intermediate) Grade III (High) Not reported

Nuclear grade Low Intermediate High Unknown

Mitotic Count

1 (less than 10 mitoses per 10 high HPF (25X objective) or 0 to 5 mitoses per 10 HPF (40X objective))

2 (10-20 mitoses per 10 high power fields (25X objective) or 6 to 10 mitoses per 10 high power fields (40X objective))

3 (Greater than 20 mitoses per 10 HPF (25X objective) or greater than 10 mitoses per 10 HPF (40X objective))

U (Unknown)

Percentage of tumor cells that are mitotic: _____%

If evaluated, Architectural grade, Tubule formation 1 (>75%) 2 (10-75%) 3 (<10%)

Unknown/Not reported

Pathologic Stage

AJCC classification version: 1st 2nd 3rd 4th 5th 6th 7th

T Stage, Pathologic T0 T1 T1a T1b T1c T1mi T2 T3 T4 T4a
 T4b T4c T4d Tis(DCIS) Tis(LCIS) Tis(Paget's) TX

- N Stage, Pathologic N0 N0(i+) N0(i-) N0(mol+) N0(mol-) N1 N1a N1b
 N1c N1mi N2a N2b N3a N3b N3c NX
- M Stage, Pathologic M0 M1 MX
- Stage Grouping 0 IA IB IIA IIA IIB IIIA IIIB IIIC IV

Pathology: Assessment of Lymph Nodes (After Definitive Surgery)

- Was sentinel node sampling performed? Yes No
- If yes, Sentinel Node Site Axillary Internal Mammary
 Supraclavicular Unknown
- If yes, Number of Sentinel Nodes Examined _____ Total No. of Other Involved Sentinel Nodes _____
- Total Number of Positive Sentinel Nodes _____
- Number of Positive Sentinel Nodes by H&E _____
- Number of Positive Sentinel Nodes by Immunohistochemistry (IHC) only _____
- Measurement of Largest Metastasis > or = 2 mm 0.2 - 2 mm <0.2mm

- Was axillary dissection performed? Yes No Unknown
- If yes, Number of Lymph Nodes Examined _____ Number of **Positive** Lymph Nodes _____
- Number of Lymph Nodes with Macrometastases _____
- Number of Lymph Nodes with Micrometastases _____

Lymph Node Assessment

Lymph Node Type	Lymph Node Involvement *	Size of Largest Nodal Met	For each type, No. of Positive Lymph Nodes
Axillary	<input type="checkbox"/>	<input type="checkbox"/> < 0.2 mm by IHC only <input type="checkbox"/> 2 mm to 2 cm <input type="checkbox"/> 0.2 to 2 mm by H&E <input type="checkbox"/> > 2 cm	<input type="text"/> <input type="text"/>
Internal mammary	<input type="checkbox"/>	<input type="checkbox"/> < 0.2 mm by IHC only <input type="checkbox"/> 2 mm to 2 cm <input type="checkbox"/> 0.2 to 2 mm by H&E <input type="checkbox"/> > 2 cm	<input type="text"/> <input type="text"/>
Supraclavicular	<input type="checkbox"/>	<input type="checkbox"/> < 0.2 mm by IHC only <input type="checkbox"/> 2 mm to 2 cm <input type="checkbox"/> 0.2 to 2 mm by H&E <input type="checkbox"/> > 2 cm	<input type="text"/> <input type="text"/>
Infraclavicular	<input type="checkbox"/>	<input type="checkbox"/> < 0.2 mm by IHC only <input type="checkbox"/> 2 mm to 2 cm <input type="checkbox"/> 0.2 to 2 mm by H&E <input type="checkbox"/> > 2 cm	<input type="text"/> <input type="text"/>

* Indicate Node Involvement: 0= Not evaluated/tested; 1= Positive Finding; 2= Negative Finding; 3= Equivocal; 4= Unknown

Marker Status (Definitive Surgery Specimen)

Estrogen Receptor (ER) Status

- Negative Positive Low Positive 1+ 2+ 3+ Unknown/Not reported
 Attempted, but technically inadequate

If reported, % cells (+) _____ %

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

Progesterone Receptor (PgR) Status

Negative Positive Low Positive 1+ 2+ 3+ Unknown/Not reported

Attempted, but technically inadequate

PgR % cells stained positive _____ %

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

Her2/neu expression by immunohistochemistry

Negative Positive Low Positive 1+ 2+ 3+ Unknown/Not reported

Attempted, but technically inadequate

If reported, % cells (+) _____ %

Staining Antibody _____

Antigen Retrieval Unknown No Yes, specify _____

Her2 status by FISH

FISH HER2/neu:chromosome 17 (HER2:cep17) Ratio _____ : _____

Amplified (HER2:cep17 ratio >2.2)

Amplified (HER2 copy number >6)

Not amplified (HER2:cep17 ratio <1.8)

Not amplified (HER2 copy number <4)

Equivocal (HER2:cep17 ratio 1.8-2.2)

Equivocal (HER2 copy number 4-6)

Not done/Not reported

Attempted, but technically inadequate

Method/Kit Used: _____

Final HER2 status

Negative Positive Equivocal Not done/Not reported

Assessment of Ductal Carcinoma In Situ (DCIS)

Is DCIS present? Yes No Unknown

Is DCIS present with invasive cancer? Yes No Unknown

If present with invasive disease, Is an extensive intraductal component (EIC) present? Yes No

Is cancerization of lobules present? Yes No

Histologic Type Comedo Apocrine Intra-cystic (encysted papillary)

(check all that apply) Cribriform Papillary Micropapillary

Clinging Other, specify _____

Does the DCIS involve the surgical margin(s)? Yes No Unknown

If YES, describe the extent of margin involvement

Single margin, focal Single margin, extensive Multiple margins

If the DCIS does **not** involve the margins, is it < 2 mm from margin(s)? Yes No

If yes, describe the extent of DCIS close to the margin

Single margin, focal Single margin, extensive Multiple margins

If the DCIS is 2mm or further from the margin, how close is the nearest margin? _____ mm.

Is Paget's disease of the nipple present? Yes No Unknown

Is microinvasive cancer present? Yes No Unknown

Assessment of Lobular Carcinoma In Situ (LCIS)

Is LCIS present? Yes No

Is LCIS present with invasive cancer? Yes No

Extent of LCIS Focal Extensive Not specified

Is LCIS at margin? Transected Greater than 10 mm Unknown
 Less than 1 mm Involved, NOS
 > or = 1 mm to 10 mm Not involved, NOS

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III. Endpoints

Timepoints

Time from registration to:

- First randomization Second randomization Third randomization
- Biologic therapy start Biologic therapy stop Hormonal therapy start
- Hormonal therapy stop Chemotherapy start Chemotherapy stop
- Radiation therapy start Radiation therapy stop
- Most extensive primary surgery Contralateral invasive disease
- Local/regional invasive recurrence Local/regional recurrence
- Distant invasive recurrence Secondary non-breast primary cancer
- Ipsilateral DCIS Contralateral DCIS Ipsilateral LCIS Contralateral LCIS
- Last assessment Last Contact or Death Death from any cause

Duration (in days/months rounded to tenths) .

Time from most extensive surgery to:

- First randomization Second randomization Third randomization
- Biologic therapy start Biologic therapy stop Hormonal therapy start
- Hormonal therapy stop Chemotherapy start Chemotherapy stop
- Radiation therapy start Radiation therapy stop
- Most extensive primary surgery Contralateral invasive disease
- Local/regional invasive recurrence Local/regional recurrence
- Distant invasive recurrence Secondary non-breast primary cancer
- Ipsilateral DCIS Contralateral DCIS Ipsilateral LCIS Contralateral LCIS
- Last assessment Last Contact or Death Death from any cause

Duration (in days/months rounded to tenths) .

Time from randomization to:

- First randomization Second randomization Third randomization
- Biologic therapy start Biologic therapy stop Hormonal therapy start
- Hormonal therapy stop Chemotherapy start Chemotherapy stop
- Radiation therapy start Radiation therapy stop
- Most extensive primary surgery Contralateral invasive disease
- Local/regional invasive recurrence Local/regional recurrence
- Distant invasive recurrence Secondary non-breast primary cancer
- Ipsilateral DCIS Contralateral DCIS Ipsilateral LCIS Contralateral LCIS
- Last assessment Last Contact or Death Death from any cause

Duration (in days/months rounded to tenths) .

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Site(s) of Progression

First recurrence/progression Local Regional Distant

Site of First Local-Regional Progression (check all that apply) Ipsilateral breast Axillary nodes Supraclavicular nodes
 Chest wall Internal mammary nodes Infraclavicular nodes
 Axilla Other

If sites other than specified, Indicate Name _____

Site of Distant Progression Brain Skin Bone
 Other, generalized NOS, carcinomatosis: _____
 Central nervous system Other CNS: _____
 Distant nodes Liver Other Visceral: _____
 Lung Other NOS: _____
 Peritoneum Pleura Other: _____ None or none known

Progressive Disease Target Lesions (At least a 20% increase in the Sum of Longest Diameters of Documentation Target Lesions, taking as reference the smallest sum recorded since the treatment started)
 Nontarget Lesions (Unequivocal progression of existing nontarget lesions)
 Appearance of one or more new lesions
 Other: _____

(Note: Record all anatomic sites of progression on the Follow-Up form for the specific disease being treated.)

Methods of Evaluation: Clinical examination CT Scan MRI (NMR) Bone Scan Other
 Chest X-ray Spiral CT Scan Ultrasound Cytology Not evaluated

Notice of New Primary (Including second primary of the contralateral breast)

Has a new primary cancer or myelodysplastic syndrome (MDS) been diagnosed? Yes No

ICD-10 Code _____