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/m^2,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 (check all that apply)
☐ Comedo
☐ Solid
☐ Cribriform
☐ Micropapillary
☐ Clinging
☐ Apocrine
☐ Intra-cystic (encysted papillary)
☐ Papillary
☐ 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

<u>Marker Status</u>

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

<u>Lymph Nodes</u>
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	☐	☐ < 0.2 mm by IHC only ☐ 2 mm to 2 cm ☐ 0.2 to 2 mm by H&E ☐ > 2 cm	☐☐
Internal mammary	☐	☐ < 0.2 mm by IHC only ☐ 2 mm to 2 cm ☐ 0.2 to 2 mm by H&E ☐ > 2 cm	☐☐
Supraclavicular	☐	☐ < 0.2 mm by IHC only ☐ 2 mm to 2 cm ☐ 0.2 to 2 mm by H&E ☐ > 2 cm	☐☐
Infraclavicular	☐	☐ < 0.2 mm by IHC only ☐ 2 mm to 2 cm ☐ 0.2 to 2 mm by H&E ☐ > 2 cm	☐☐

*** 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 (check all that apply) ☐ Comedo ☐ Apocrine ☐ Intra-cystic (encysted papillary) ☐ 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
☐ Less than 1 mm
☐ > or = 1 mm to 10 mm
☐ Greater than 10 mm
☐ Involved, NOS
☐ Not involved, NOS
☐ Unknown

CONTINUED ON NEXT PAGE

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) ☐☐.☐

CONTINUED ON NEXT PAGE

Site(s) of Progression

First recurrence/progression ☐ Local ☐ Regional ☐ Distant

Site of First Local-Regional Progression ☐ Ipsilateral breast ☐ Axillary nodes ☐ Supraclavicular nodes
(check all that apply) ☐ 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 _____