Clinical Trial Screening and Accrual Log

This CRF corresponds to the electronic log located at https://cabig.nci.nih.gov/community/screenaccruallog

QUESTIONS? TECHNICAL/IT: ncicb@pop.nci.nih.gov CONTENT: NCINCCCPLogSupport@mail.nih.gov

Patient Identification Number: XXXXXXXX
Record the Patient ID for your records

1. **Date of patient screening:**
   (ex. MM/DD/YYYY)

PATIENT DEMOGRAPHICS

2. **Ethnicity (**select only one**):** ☐ **Hispanic or Latino** ☐ **Non-Hispanic/Latino** ☐ **Unknown**
3. **Race:** ☐ **American Indian or Alaska Native** ☐ **Native Hawaiian or Other Pacific Islander**
   ☐ **Asian** ☐ **Black or African American** ☐ **White** ☐ **More Than One Race**
   ☐ **Not Reported, Patient Refused** ☐ **Not Reported, Data Not Available**
   ☐ **Unknown, Patient Unsure of Race**
4. **Gender (**select only one**):** ☐ **Male** ☐ **Female**
5. **Age (ex 43):** _____

PROTOCOL SCREENING METHODS

6. **Protocol for which the patient was screened (**select only one**):** Definitions on page 6.

☐ **CALGB 40603 (Neoadjuvant Breast)**

☐ **CALGB 80702 (Adjuvant Stage III Colon)**

☐ **CALGB 90601 (Advanced TCC)**

☐ **ECOG 1305 (1st line Rec/Met H&N)**

☐ **ECOG 1505 (Lung)**

☐ **ECOG 1609 (Melanoma)**

☐ **ECOG 5508 (Maint. NSCLC)**

☐ **NSABP B-43 (Breast DCIS)**

☐ **NSABP B-47 (Adjuvant Breast)**

☐ **NSABP P-5 (Prevention Colon)**

☐ **SWOG 1007 (Adjuvant Breast)**

☐ **SWOG 0702 Obs ONJ Zoledronic Acid (Cancer Control**

7. **What method(s) were used to identify this patient for protocol screening (**select all that apply**):**

- ☐ **Cancer/tumor registry**
- ☐ **Chart review**
- ☐ **Multidisciplinary/disease site conferences**
- ☐ **Pathology report**
- ☐ **Patient care rounds**
- ☐ **Patient self referral**
- ☐ **Patient navigator**
- ☐ **Pharmacy/chemotherapy list**
- ☐ **Provider referral: NCCCP investigator**
- ☐ **Provider referral: outside institution**
- ☐ **Provider referral: within institution**
- ☐ **Response to advertisement**
- ☐ **Review of clinic schedule**
- ☐ **Review of surgical schedule**
- ☐ **Tumor board**

8. **Was the patient navigator used in identifying the patient for screening:** ☐ **Yes** ☐ **No**

9. **If the patient navigator was involved, indicate how they were involved (**select all that apply**):**

- ☐ **Navigator obtained consent for treatment**
- ☐ **Navigator screened the patient**
- ☐ **Navigator referred patient to the research team**

PROTOCOL SCREENING

10. **Did the patient enroll in the protocol:** ☐ **Yes** ☐ **No**

11. **If the patient did not enroll in the protocol, indicate the reason why (**select only one**):**

- ☐ **Patient did not meet trial eligibility criteria (**skip to question 13**)**
- ☐ **Patient was eligible but declined participation (**skip to question 15**)**
- ☐ **Patient was eligible but MD declined to offer participation (**skip to question 16**)**
- ☐ **Patient was eligible but started treatment prior to completion of screening (**skip to question 12**)**
- ☐ **Patient was eligible but study suspended (**skip to question 17**)**

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one**):**

☐ **Insufficient medical records at time of screening**

☐ **Patient not referred to the research team**

☐ **Recurring patient/ not new patient**

☐ **Urgency to initiate treatment**

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply**):**

☐ **Abnormal labs**

☐ **Abnormal organ function**

☐ **Age criteria**

☐ **Allergy/intolerance to study related drug**

☐ **Co-morbidities**

☐ **Does not meet biomarker testing criteria**

☐ **Inappropriate stage, subtype, grade, or surgical margin**

☐ **Insufficient or unavailable pathologic samples for study**

☐ **Intolerance to study drug or related drugs**

☐ **No measurable disease**

☐ **Patient had progressive disease**

☐ **Performance status**

☐ **Prior therapy**

☐ **Prohibited medication**

☐ **Second cancer**

☐**Time requirement from surgery or therapy**

14. Skip---Question Was Removed from Log

15. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all that apply**):**

- ☐ **Cultural/religious issues**
- ☐ **Did not keep appointment**
- ☐ **Family member influenced against trial participation**
- ☐ **Financial concerns/indirect costs (work, etc)**
- ☐ **Insurance company denied coverage**
- ☐ **Insurance company refused to pay for additional testing**
- ☐ **Lack of awareness/education about trials**
- ☐ **Language barrier/ lack of access to interpreter**
- ☐ **Lost to follow-up**
- ☐ **Mistrust of research**
- ☐ **No desire to participate in research**
- ☐ **No insurance coverage**
- ☐ **Palliative care/hospice**
- ☐ **Patient declined to be retested per protocol**
- ☐ **Patient preferred another trial**
- ☐ **Perceived side effects/toxicities too great**
- ☐ **Preference for standard treatment**
- ☐ **Preferred no treatment**
- ☐ **Refused to have re-biopsy or further tissue collection**
- ☐ **Second opinion/transfer of care**
- ☐ **Social issues(Housing, childcare)**
- ☐ **Travel & transportation issues**

16. If the patient was eligible but the MD declined to offer participation, indicate the physician-related reason why (select all that apply**):**

- ☐ **Concerns over patient non-compliance/lack of social support**
- ☐ **Drug unavailability**
- ☐ **Insurance denied coverage**
- ☐ **Insurance company refused to pay for additional testing**
- ☐ **Lack of adequate reimbursement**
- ☐ **Lack of knowledge/awareness of the trial by MD/Research staff**
- ☐ **Lack of MD/Research staff to offer patient the trial**
- ☐ **Lack of time for MD/Research staff to offer patient the trial**
- ☐ **Language barrier/lack of access to interpreter**
- ☐ **Medical concerns re: Comorbidities not included in eligibility**
- ☐ **Medical concerns re: patient tolerating treatment/performance status**
- ☐ **Non-participating MD**
- ☐ **Patient referred out**
- ☐ **Physician declined to have patient retested per protocol**
- ☐ **Preferred to offer palliative care**
- ☐ **Preferred to offer different trial**
- ☐ **Preferred to offer no treatment**
- ☐ **Preferred to offer standard of care**
- ☐ **Refused to have re-biopsy or further tissue collection**

17. If there was a language barrier, indicate the language spoken (select only one**):**

☐ **Chinese**

☐ **Filipino**

☐ **French**

☐ **Japanese**

☐ **Korean**

☐ **Russian**

☐ **Spanish**

☐ **Vietnamese**

☐ **Hmong**

☐ **Italian**

☐ **Somalian**

☐ **Hungarian**

18. Is the patient rural per NCCCP/site criteria?

☐ **Yes**

☐ **No**

Protocol Screening Definitions

1. **CALGB 40603** Untreated, resectable breast cancer, HER-2 Negative, Hormone Receptor (ER/PR) poor (=<10% by IHC)
2. **CALGB 80702**: Completely resected Stage III colon adenocarcinoma and no prior chemotherapy.
3. **CALGB 90601 (Advanced Uroepithelial Neoplasm)**: Locally advanced or metastatic urinary tract transitional cell CA with no prior chemotherapy for metastatic disease.
4. **ECOG 1305 (1st line Rec/Met H&N CA):** Loco regional recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck without prior chemotherapy for recurrent or metastatic disease.
5. **ECOG E1505 (Lung)**: Resected non-small cell lung carcinoma Stage IB – IIIA less than 12 weeks post resection
6. **ECOG E1609 (Melanoma):** Completely Disease free, Surgically resected, Stage IIIb, IIIc,M1a or M1b
7. **ECOG E5508 (Maint. NSCLC)**: Stage IV nonsmall cell, nonsquamous cell lung CA and no prior advanced stage disease chemotherapy.
8. **NSABP B-43 (Breast DCIS)**: Female breast DCIS following lumpectomy.
9. **NSABP B-47 (Adjuvant Breast)**: Resected invasive breast CA Stage II and III with T1 to T3, low Her-2, and no neoadjuvant chemotherapy.
10. **NSABP P-5**: Stage I or II colon adenocarcinoma completely resected within the last 12 months.
11. **SWOG S0702 ONJ – Zoledronic Acid (Cancer Control):**
    i. Bone involvement by Multiple Myeloma, Solid Tumor Neoplasms, or other malignancy with an indication for IV bisphosphonate therapy.
    ii. No prior IV bisphosphonate therapy or IV bisphosphonate therapy of < 90 days prior to registration.
12. **SWOG 1007 Adjuvant Breast** Node positive 1-3, Hormone Receptor positive, HER2 Neg

Log Entry Guidance

Instructions: The chart below is intended to help you easily locate a Log answer choice for your patient. Follow the steps below to help guide your data entry into the online Log.

Step 1: Find your patient's scenario in the "Patient Scenario" column below.
Step 2: Look in the column to the right ("Suggested Action") to see guidance on how to enter the patient's information into the Log.
Step 3: If you're still unsure, email the Log Support Team at NCINCCCPLogSupport@mail.nih.gov.

Log Question Number	Patient Scenario	Suggested Action
ID of Patient for screening (Q7)	• Non-MD referrals	• Select one of the following answer options: o "Provider referral: NCCCP investigator" o "Provider referral: within institution" o "Provider referral: outside institution"
Protocol Screening		
Reason Not Enrolled (Q11)	• Language barrier	• Select "Patient was eligible but MD declined to offer participation" in Q11, then select "Language barrier/lack of access to interpreter" in Q16.
	• Patient did not have cancer	• *DO NOT ENTER PATIENT INTO LOG*
	• Patient does not meet protocol screening definition (definitions can be found in CRF)	• *DO NOT ENTER PATIENT INTO LOG*
Eligibility-Related (Q13)	• Incomplete or different pathology	• *DO NOT ENTER PATIENT INTO LOG until final pathology*
	• Inappropriate stage/grade	• *DO NOT ENTER PATIENT INTO LOG until final staging/pathology*
	• On other drugs, e.g., statin	• Select "Prior therapy"
	• Incomplete staging	• *DO NOT ENTER PATIENT INTO LOG*
	• Too low or high Oncotype score	• Select "Does not meet biomarker testing criteria"
	• Unknown	• *DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop*
	• Metastatic disease	• Select "Patient had progressive disease"
	• Patient expired during the screening process	• Select "Patient had progressive disease"

Patient-Related (Q15)	• Did not keep appointment	• Select "Lost to follow-up"
	• Unknown	• *DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop*
	• Study closed	• *DO NOT ENTER PATIENT INTO LOG*
MD-Related (Q16)	• Dementia/cognitive problems	• Select "Medical concerns re: Co-morbidities not included in eligibility"
	• Medical concerns re: age/frailty of patient	• Select "Medical concerns re: Co-morbidities not included in eligibility"
	• Unknown	• *DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop*
	• MD preferred other Rx	• Select "Preferred to offer standard of care" OR "Preferred to offer different trial"
		Chart last updated 2012May15