TrACER (S1415CD) NEWSLETTER

May 2017

TrACER session at April SWOG Group Meeting

TrACER: A Pragmatic Trial Assessing CSF Prescribing Effectiveness and Risk

This pragmatic trial is designed to test an intervention to increase compliance with guidelines, and generate evidence to assess effectiveness of Primary Prophylactic CSF (PP-CSF) on reducing rates of FN for patients receiving intermediate-risk chemotherapy regimens. TrACER is the first trial of its kind and is sponsored by SWOG, a part of the National Clinical Trials Network. The trial is led by Dr. Scott Ramsey at HICOR and funded in part by PCORI.

STUDY UPDATES

- As of 5/15/17, we have **393 patients registered across 30 components** (10 Cohort, 6 Usual Care, 6 Intervention Arm 3, 8 Intervention Arm 4).
- As of 5/15/17, **15 of our 24 intervention components** have completed their order change process and are open for enrollment.

CONGRATULATIONS AND THANK YOU

Congratulations to the following sites who have completed their order change process as of 5/15/17:

- **Tripler Medical Center** in Honolulu, HI
- **Lewis Cancer and Research Pavilion at Saint Joseph's** in Savannah, GA

Congratulations to the following sites for enrolling their first patient as of 5/15/17:

- **Medical Oncology and Hematology Associates** in Des Moines, IA
- **St John Hospital and Medical Center** in Grosse Pointe Woods, MI
- **Sanford Medical Center** in Fargo, ND
- **University of New Mexico Cancer Center** in Albuquerque, NM
- **Presbyterian Kaseman** in Albuquerque, NM
- **Tripler Medical Center** in Honolulu, HI

Thank you all for your participation in TrACER!

HICOR

SWOG
Leading cancer research. **Together.**

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

FAQS OF THE MONTH - May, 2017

1. **When should patient baseline questionnaires be completed?**
   Baseline patient questionnaires should be completed after consent has been obtained and prior to the initiation of chemotherapy, and thus may be completed before or after registration. See Section 15.2 of the protocol.

2. **Are patients who had surgery or radiation only for early stage disease and then progressed or have a recurrence of same disease site who have not been treated with prior chemotherapy eligible?**
   Yes, these patients are potentially eligible under Sections 5.1a, 5.2a, and 5.2b.

3. **What is the difference between Intermediate-risk paclitaxel q21 days and Low-risk Paclitaxel (Abraxane) weekly?**
   Intermediate-risk paclitaxel q21 days is given at 175 mg/m2 on just day 1 of the cycle. Low-risk paclitaxel weekly is given at 80mg/m2 every 7 days, which could be defined in orders as "weekly" or "every 21 days on days 1, 8, 15."

HELPFUL INFORMATION/REMINDERS

- **Onstudy: Initial Diagnosis Date and Prior Therapy**
  The baseline Onstudy Form requires the date of initial diagnosis and prior therapy received. The date of initial diagnosis should be the date your patient was first diagnosed with breast cancer, non-small cell lung cancer, or colorectal cancer. The prior treatment reported should include all treatment patient has received since their initial diagnosis date.
- **Screening Reports**
  Our funders, PCORI, are requiring that we report out screening data for TrACER. At the beginning of each month, we need to report **the total number of cumulative screened patients** for each open site. **Please have this number available and ready to send to Ari each month.** Every six months (in January and July), we need to report out the total number of cumulative screened patients, how many patients were eligible, reasons for ineligibility, and reasons patients declined to participate. If you need a log to track this, please contact Ari and she can send you one.

TrACER Statement:
The TrACER study is in no way endorsing the inclusion or exclusion of G-CSF in a chemotherapy order for any particular patient. It is still the duty of the provider to consider the necessity of G-CSF for each and every patient and act in a way that is consistent with both guidelines and the patient's needs.

For more information on this, please see the attached one-page summary on TrACER.

Contact Us
Site Requirements, including regimen questions: HICOR, TrACER@fredhutch.org; phone: 206-667-7624
Patient eligibility, study procedures, and data submission: SWOG Data Ops, email: cancercontrolquestion@crab.org; phone: 206-652-2267