TrACER (S1415CD) NEWSLETTER

July 2017

STUDY UPDATES

- As of 7/10/17, we have **594 patients registered across 34 components** (11 out of 13 Cohort components, 7 out of 8 Usual Care components, 7 out of 12 Intervention Arm 3 components, and 9 out of 12 Intervention Arm 4 components).
- **20 of our 24 intervention components** have completed their order change process and are open for enrollment! We're so close to having all of our intervention components open!
- A manuscript developed regarding the design of TrACER was accepted into the Journal of Comparative Effectiveness Research. The abstract is available online, ahead of print, here: http://bit.ly/2us9Kuj

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.

CONGRATULATIONS AND THANK YOU TO...

The following components for completing their order change process as of 7/10/17:

- ★ **Marshfield WINCORP** in Marshfield, WI
- ★ **Geisinger Medical Center** in Danville, PA
- ★ **Louisiana State University Health Science Center** in New Orleans, LA
- ★ **Saint Alphonsus Regional Medical Center** in Boise, ID
- ★ **William Beaumont Hospital** in Troy, MI

The following components for recently enrolling their first patients as of 7/10/17:

- ★ **Christus Saint Vincent Regional Cancer Center** in Santa Fe, NM
- ★ **Marshfield WINCORP** in Marshfield, WI
- ★ **Lewis Cancer and Research Pavilion at Saint Joseph's** in Savannah, GA

The following components for reaching at least 75% of the accrual target as of 7/10/17:

- ★ **Mercy Hospital Springfield** in Springfield, MO
- ★ **Novant Health Forsythe Medical Center** in Winston-Salem, NC

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

HELPFUL INFORMATION/REMINDERS

Six Month Forms
The 6 Month Status Update and 6 Month Febrile Neutropenia Log are due at 6 months from patient's registration. The Use and Copayment Survey is due by 6 months: per Section 14.4d of the protocol, it can be completed and submitted after the patient has received the necessary documentation to complete it.

Regimen Changes
Occasionally a provider will decide to switch regimens after registration but prior to when the patient actually starts systemic therapy. For example, a provider originally orders TC, then decides to order just T for a patient. If this happens, do not modify the original order: it must be replaced with a new order. The provider should discontinue the original regimen order and order a new regimen separately. This will ensure that the intervention is delivered in conjunction with the actual regimen received by the patient.

Adverse Events
Only adverse events attributable to CSF use should be reported on the CSF Adverse Event Form. If a patient is not prescribed CSF during their first cycle of initial systemic therapy, then there are no CSF-attributable events for that patient.

ACCRUAL TARGETS

Unlike most studies, the components participating in TrACER have each committed to accrue a specific number of patients to the study. **We are monitoring accrual and will notify components when they are nearing their component-specific accrual targets. Once an accrual target has been reached by a specific component, that category of patient will be closed to accrual in OPEN for that component only.**

Overall accrual. The accrual target for Cohort components is 56 eligible patients (up to 60 patients total). The accrual target for Usual Care and Intervention components is 90 eligible patients (up to 99 patients total).

FN Risk Level accrual. We will also be monitoring accrual for Usual Care and Intervention components by FN risk category. Accrual to low and high risk regimens is limited to 45 eligible patients per component, and accrual to intermediate risk regimens is limited to 45 eligible patients per component. Cohort components have no accrual restrictions based on FN risk level.

To help the components manage their recruitment efforts, we will notify components as they draw near to their component-specific accrual targets. **Cohort components** will be alerted when they have reached 90% and 100% of their overall accrual target. **Usual Care** and **Intervention** components will be alerted when they have reached 90% and 100% of their various accrual targets.

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