TRACER (S1415CD) NEWSLETTER

October 2018

STUDY UPDATES

- **As of 10/22/2018, there are 2,227 patients registered to the study.**

THANK YOU TO OUR TOP ACCRUERS

Congratulations to Spartanburg Medical Center in Spartanburg, SC, Cancer Care Specialists of Central Illinois in Decatur, IL, and to John H Stroger in Chicago, IL for reaching 100% accrual!

This site has reached at least 90% of overall accrual:

- ★ Sanford Medical Center in Fargo, ND

These sites have reached at least 75% of their overall accrual:

- ★ Saint Luke's Mountain States Tumor Institute in Boise, ID
- ★ Geisinger Medical Center in Danville, PA
- ★ Marshfield Clinic in Marshfield, WI

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.

ACCRUAL OPPORTUNITY

TrACER is not on target to meet its accrual goals. Effective immediately, the study is increasing accrual caps for all interested randomized components (Group 2, Group 3, and Group 4). Components are invited to accrue up to 100 low and high risk patients and up to 100 intermediate risk patients. Risk levels that were previously closed to accrual have been re-opened.

Additional accrual to the increased limits is voluntary. However, all sites should attempt to accrue at least 49 low and high risk patients and 50 intermediate risk patients.

Any components choosing to accrue additional patients will continue to receive the additional $750 payment for Patient Survey Submissions, as stated on the S1415CD Funding Memo.

Please note that Cohort sites (Group 1) will continue to accrue up to 60 patients.

Overall accrual limits for the study will not change. These accrual allowances are consistent with the current protocol and no protocol revision will be forthcoming.

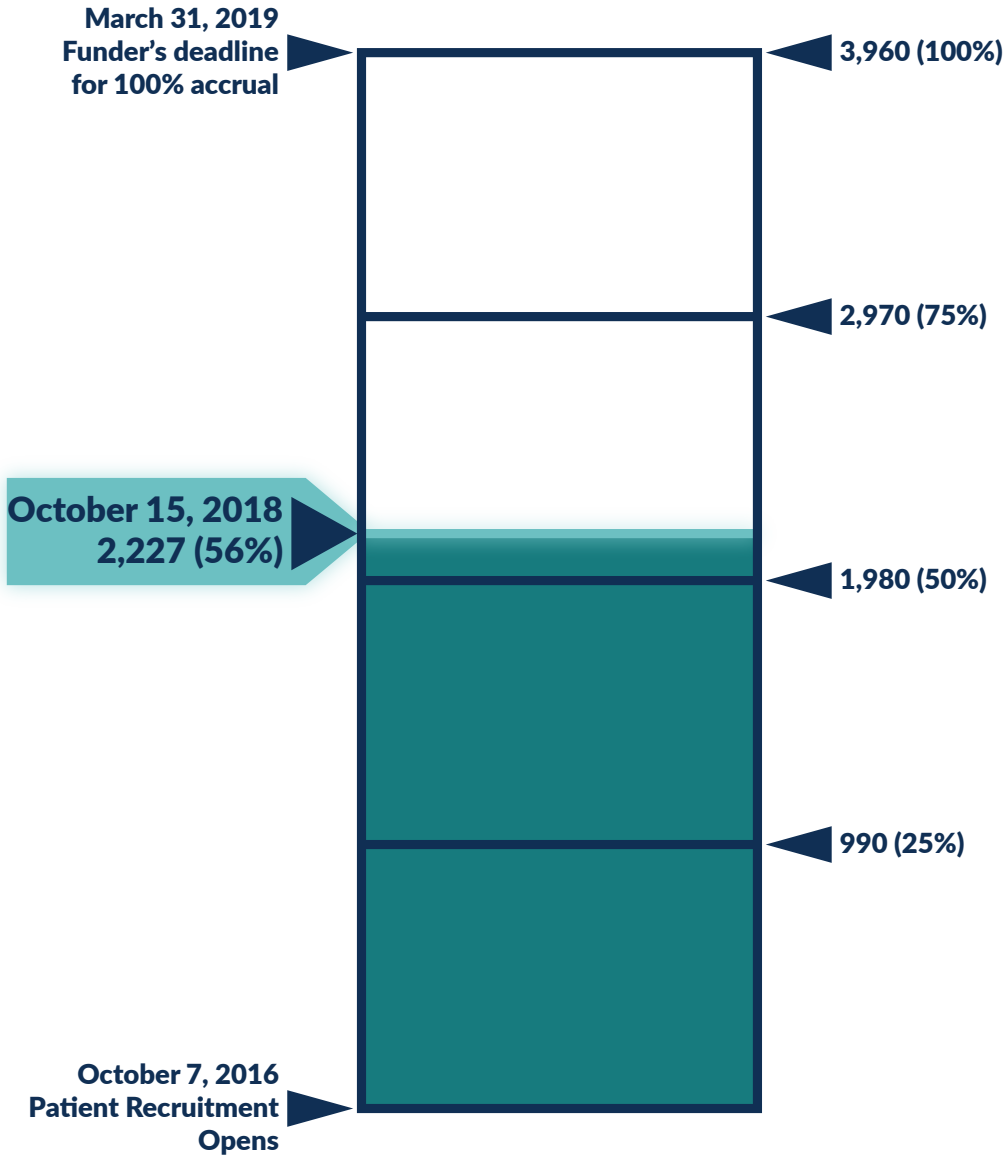
FEBRILE NEUTROPENIA DEFINITION

Febrile neutropenia is defined as: an absolute neutrophil count (ANC) < 1,000/uL and a single temperature of > 38.3 degrees C (101°F) or a sustained temperature of ≥ 38°C (100.4°F) for more than one hour (NCI CTCAE Version 4.0). Febrile neutropenia is the study's endpoint - please report all instances of febrile neutropenia on the appropriate study forms.

SERIOUS ADVERSE EVENTS (SAES)

Use CTEP-AERS reporting for SAEs related to CSF use. Only SAEs related to CSF use and meeting the criteria in protocol Section 16.1e should be submitted through CTEP-AERS. If a patient is not prescribed CSF during their first cycle of initial systemic therapy, there are no CSF-attributable events for that patient, and CTEP-AERS should not be used for reporting.

TrACER Total Accrual as of October 22, 2018



Contact Us

Site Requirements, including regimen questions: HICOR ▪ TrACER@fredhutch.org ▪ 206-667-7624
Patient eligibility, study procedures, and data submission:
SWOG SDMC ▪ cancercontrolquestion@crab.org ▪ 206-652-2267