TRACER (S1415CD) NEWSLETTER

Nov. 2016

STUDY UPDATES

- TrACER was officially activated on October 26, 2016 with the registration of our first patient
- As of 11/15/16, we have 37 components participating in the study:
  - 14 Cohort sites
  - 6 Usual care sites
  - 8 Intervention Arm 3 sites
  - 9 Intervention Arm 4 sites
- We are actively recruiting for **1 additional** component for our final round of randomization
- Study materials now available via SWOG.org and CTSU.org
- TrACER newsletters will be distributed once per month

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

Congratulations to the following sites!

Mercy Hospital Springfield in Springfield, MO for registering the FIRST patient to the TrACER study!

Columbia University in New York, NY for being the FIRST intervention site to complete the order change process in their system!

The following sites that have registered patients thus far:

Component Name	NCI Code	Total Accrual
Carle Cancer Center	IL168	1
Cancer Center of Kansas- Main Office	KS034	2
Oncology Hematology Associates	MO042	2
Mercy Hospital Springfield	MO043	1

Thank you for all of 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- NOV. 2016

1. **When is the last possible time we can register a patient? When should their baseline questionnaires be completed?**

   Patients may be registered to the study as late as their first day of chemotherapy, as long as registration happens prior to initiation of chemotherapy. See sections 5.2b and 13.1 of the protocol. Baseline patient questionnaires should be completed prior to initiation of chemotherapy.

2. **What is the maximum number of patients each component can enroll?**

   For randomized sites, the maximum number of patients is 99 per component. For cohort sites, the maximum number of patients is 56. The study team will monitor for eligibility and communicate to sites when to stop accruing patients for each risk level. See protocol section 11.2.

3. **(INTERVENTION SITES ONLY): Do I need to modify or add standing orders for just intermediate risk regimens?**

   For this study, you will be asked to modify or touch ALL risk regimens included on the algorithm (Appendix 18.1) that your site uses. This includes standing orders and system notes that alert the ordering physician that a regimen is designated high, intermediate or low risk per guidelines and notes the randomization arm for intermediate risk regimens. For Intervention Arm 3, this means adding automatic INCLUSION orders/system notes for high and intermediate risk regimens, and automatic EXCLUSION orders/system notes for low risk regimens. For Intervention Arm 4, this means adding automatic INCLUSION orders/system notes for high risk regimens, and automatic EXCLUSION orders/system note for intermediate and low risk regimens. Please refer to Table 3 on page 11 of the Order Change Protocol for suggested wording of system notes.

HELPFUL INFORMATION

- If you have any sub-components that will be participating in the trial with you (share the same Electronic Health Record (EHR)), please be sure to send us their CTEP IDs. If we do not have their CTEP IDs, they will not be able to register patients.
- Sites must obtain local IRB for this study; CIRB is not available. Let the TrACER team know if you run into any problems with this process.
- Reminder: Patient eligibility is not dependent on whether a patient will be receiving CSF; CSF use is one of the study outcomes. See Protocol Sections 1.0 and 5.0.

Intervention sites:

- Please do not begin accruing patients until the HICOR team has approved your changes.
- If you have still not completed the clinic characterization survey, please complete the **survey** by November 30, 2016 and contact the TrACER team to set up a phone call.
- Once you have an implementation plan in place, please contact TrACER@fredhutch.org to receive the Implementation questionnaire. **The completed questionnaire must be reviewed by HICOR prior to making changes in your system.**
- Contact the TrACER team if you need any consultant assistance in your order change process. We currently have consultants on call for EPIC, Aria, Mosaiq, and Cerner. We are happy to source consultants for other systems upon request.

Contact Us

Site Requirements, including regimen questions: HICOR, email: 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