TRACER (S1415CD) NEWSLETTER

December 2016

STUDY UPDATES

- We have officially recruited **ALL** sites for the TrACER study. We will soon be randomizing our second group of sites.
- Due to the PCORI funding requirements, sites will need to submit **patient screening data** every 6 months beginning in January (see the email sent 12/12/16).
- We will be holding webinars in February to discuss study progress and have Q & A with the Study Team. Outlook invitations were sent 12/8/16. Please RSVP with the times you are available. The dates for the webinars are as follows:
  - **Cohort/Usual Care Arms:**
    2/6/17 10-11AM PST (12-1PM CT, 1-2PM EST) or
    2/7/17 9-10AM PST (11AM-12PM CT, 12-1PM EST)
  - **Intervention Arms:**
    2/7/17 12-1PM PST (2-3PM CT, 3-4PM EST) or
    2/8/17 11AM-12PM PST (1-2PM CT, 2-3PM EST)

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

Congratulations to the **Illinois CancerCare** in Peoria, IL, for completing the order change process in their system!

Accruing Sites as of 12/12/16

Institution	NCI Code	Total Registration
Mercy Hospital Springfield	MO043	10
Cancer Center of Kansas - Wichita	KS034	5
Greenville Health System Cancer Institute-Easts	SC053	5
Carle Cancer Center (IL168)	IL168	3
Illinois CancerCare-Peoria	IL101	3
Adena Regional Medical Center	OH182	2
CoxHealth South Hospital	MO042	2
Greenville Health System Cancer Institute-Easts	SC060	2
Columbia University/Herbert Irving Cancer Center	NY024	1
Greenville Health System Cancer Institute-Easts	SC056	1
Novant Health Forsyth Medical Center	NC047	1
	Total (11 Institutions)	**35**

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

FAQS OF THE MONTH - DECEMBER, 2016

1. **If a patient is consented to the study but the physician overrides the default CSF order, is the patient still eligible to participate in the study?**

   Yes. We will still collect data on that patient for the study. Whether a patient received CSF is a primary objective of the study. See section 1.1a.

2. **My patient is on a cycle with fewer than 14 days in the cycle. When should I submit "end of first cycle" data?**

   Regimens that normally have a cycle length of fewer than 14 days will be reported as a 14-day cycle for purposes of study data collection. Specifically, regimens with a cycle length of 1 day or 7 days will have data collection at Day 14 for "end of first cycle" data, including patient completed questionnaires, using Day 14 as the Cycle End Date. See Section 14.4 for data submission requirements and Section 18.1 for study-allowed regimens and regimen-specific cycle lengths.

3. **(INTERVENTION SITES ONLY): We are unsure what type of GCSF and what dosage to include in our standing order. Do you provide recommendations?**

   No, this is beyond the scope of the study. Prescribing practices should be determined by the physician at your site. If you have questions on a specific regimen, we may be able to send you references for PP-CSF prescribing, but the ultimate dosing decisions should be left to your physicians.

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 included on the list for access to the study database.
- Sites must obtain local IRB approval for this study; CIRB is not available. Let the TrACER team know if you run into any problems with this process.

Intervention sites:

- **Do not begin accruing patients until the HICOR team has approved your system changes.**
- 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.

Thank you all for your participation in TrACER!

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