TRACER (S1415CD) NEWSLETTER

April 2017

STUDY UPDATES

New study materials are available on the protocol page for download including:

- A study overview for investigators
- A study overview for study coordinators
- Resources for patients for CSF coverage
- A clinic group diagram.

UPCOMING EVENTS

Mark your calendars! On **Thursday, April 27th from 10AM-12PM PST** we will host a TrACER update meeting at the SWOG group meeting in San Francisco. The meeting will provide an opportunity for participating sites to hear important updates from the study team, meet and share best practices for setting up standing orders, patient recruitment and other pertinent topics. Light refreshments will be provided. We hope to see you all there!

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 following sites who have completed their order change process as of 4/10/17:

- **Presbyterian Kaseman** in Albuquerque, NM
- **Medical Oncology and Hematology Associates** in Des Moines, IA

Congratulations to the following sites for enrolling their first patient as of 4/10/17:

- **West Michigan Cancer Center** in Kalamazoo, MI
- **CHI Health St Francis** in Grand Island, NE
- **Contra Cost Regional Medical Center** in Martinez, CA
- **Essentia Health Cancer Center** in Duluth, MN
- **Queen's Medical Center** in Honolulu, HI
- **Bozeman Deaconess Cancer Center** in Bozeman, MT
- **St Joseph Mercy Hospital** in Ann Arbor, MI
- **Swedish Cancer Institute** in Seattle, WA
- **Billings Clinic Cancer Center** in Billings, MT

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 - APRIL 2017

1. **If a patient is scheduled to receive a chemotherapy regimen listed in Section 18.1 but at a reduced dose, are they eligible to be registered to this study?**

   No. Subjects getting non-standard treatment are not eligible for this study. The expectation is that the administration of regimens listed in Section 18.1 should be usual or standard and generally match up with NCCN guidelines.

2. **Is there a SWOG standard regarding the amount of time between the date a patient signs the informed consent and the date the site registers the patient?**

   Always follow your institutional policies regarding patient consent. Per the SWOG Regulatory Guidance, September 2016 document (found on the QA/Audits page of www.SWOG.org), if there is a substantial delay from the time the patient signs consent and is enrolled in a study (> 30 days), it is **recommended** that the information contained in the consent form be reviewed with the subject prior to initiating any research procedures with the subject and the discussion documented in the research record. The patient must be re-consented if there have been any significant updates to the consent (new study design, added risk, etc.). Re-consent is not required if there are no changes or only minor changes to the consent.

HELPFUL INFORMATION/REMINDERS

Febrile Neutropenia Event Reporting

Report any and all febrile neutropenia events at the end of the first cycle, regardless of attribution, on the S1415CD Febrile Neutropenia form and the S1415CD 6 Month Febrile Neutropenia Log.

HIGHLIGHT ON: TRACER'S EXTERNAL STAKEHOLDER ADVISORY GROUP!

The External Stakeholder Advisory Group (ESAG) is comprised of 21 leaders in health care from across the country who provide input and guidance during each stage of the TrACER Study, from study design to implementation and dissemination activities. Each project year, the ESAG convenes over four webinars and one in-person meeting to discuss study updates, issues and challenges with the research team. The group has shaped the development and refinement of all study-related materials and offers critical feedback on the execution and future directions of the study. In addition to advising and supporting this study, ESAG members strive to improve cancer care in their professional careers as prominent patient advocates, researchers and academics, directors of advocacy organizations and cancer care programs, independent advisors and consultants, medical oncologists, nurses, pharmacists, payers, national guidelines experts, and a medical ethicist. The group was formed in Fall 2014 during the proposal planning phase of the trial and expanded in Spring 2016 to include six SWOG Patient Advocates from the Cancer Care Delivery, Breast, Lung and GI Committees.

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