# TrACER Study (S1415CD)
# Trial Assessing CSF prescribing Effectiveness and Risk

**PURPOSE:** This is supplemental information for research staff and providers to support and clarify information about patient participation in the TrACER study in congruence with the approved protocol and consent. See the S1415CD protocol at http://swog.org/.

*This is not intended for patient distribution. Materials presented to patients require IRB approval.*

## Study Overview for the Study Coordinator

### ABOUT THE STUDY

- The research team is looking at the prescribing and use of primary prophylactic colony stimulating factors (PP-CSFs) among patients with breast, colorectal, and non-small cell lung cancer receiving chemotherapy.
- National oncology guidelines recommend using PP-CSFs if a planned chemotherapy treatment is at high risk of causing febrile neutropenia (FN). Guidelines do not recommend routine use of PP-CSFs for chemotherapy treatments designated as low risk for febrile neutropenia. Guidelines say to consider use for chemotherapy treatments designated as intermediate risk.
- Although evidence-based clinical practice guidelines for prescribing primary prophylactic colony stimulating factors (PP-CSF) have been available for nearly two decades, multiple studies show that the gap between best scientific evidence and clinical practice is wide for PP-CSF prescribing. Between 55% and 95% of PP-CSF prescribing is inconsistent with evidence-based national guidelines.
- When used in recommended settings, PP-CSF has clear benefits for patients, including reducing the risk of hospitalization and death due to infection. Therefore, it is critically important to ensure that PP-CSF is prescribed when supported by evidence.
- This pragmatic trial is designed to test an intervention to increase compliance with guidelines while also generating high quality evidence to assess effectiveness of PP-CSF on reducing rates of FN for patients receiving intermediate-risk chemotherapy regimens.
- The study does NOT dictate if a patient will or will not receive PP-CSF. Physicians can override the study orders at their discretion based on what they feel is best for each individual patient.
- The research team hopes to learn more about patient experiences with the symptoms, side effects, and costs associated with CSFs through several questionnaires.
- 24 of the 46 clinics have had their prescription order systems changed by the study team to include or exclude orders for CSFs based on whether the planned cancer treatment poses a high, moderate* or low risk of febrile neutropenia.
- For more information on study background, please reference the study protocol.

* In the informed consent, the phrase “moderate risk” was used to describe patients at intermediate risk for febrile neutropenia to enhance readability among patients. Intermediate risk is the correct clinical term used in the NCCN guidelines.

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Each component has been assigned to one of the four study groups:

- Group 1 (Cohort)
- Group 2 (Randomized to Usual Care)
- Group 3 (Randomized to Intervention)
- Group 4 (Randomized to Intervention)

See Component Schema in the S1415CD Protocol for a description of each group.

**What is involved?**

- Patient care is not impacted by study participation. All patients at the site are subject to the same standing orders. A patient's cancer treatment and any risks related to treatment should be the same whether or not they participate in this study.
- Patients are consenting to let the research team gather data from their medical records and from patient questionnaires.
- Patients will complete questionnaires at three different time points in their treatment, which should take around 15-20 minutes each. Patients will also have the option to take the questionnaire home to complete.
- There are no experimental drugs involved in this trial.
- Participation in this study does not involve extra testing, treatment or procedures.
- Patients are allowed to participate in other clinical trials while participating in TrACER. However, patients must not be participating in or plan to participate in other clinical trials that involve investigational systemic cancer treatments or investigational uses of CSF while on this study. See protocol section 5.0 for full eligibility criteria. For questions, please contact the study office at CancerControlQuestion@crab.org or call 206-652-2267.

**What are the possible risks of taking part in the study?**

- This study primarily focuses on prescribing methods, not the effects of CSFs. However, as with any medication, potential side effects should be discussed when a clinician chooses to prescribe CSFs.

**What are the possible benefits of taking part in the study?**

- By participating in this study, the patient will help provide critical information to the research team and providers about use of CSFs with certain cancer treatments, an area where evidence is severely lacking.

**What are the patient costs of taking part in this study?**

- The study does not cover the costs of CSFs. If the physician decides to prescribe CSFs, the medication – as part of routine treatment – will be processed through the patient's insurance following the same procedures as any other medications that may require insurance approval. If the patient is uninsured and a self-payer, the individual should be made aware of the out-of-pocket costs that will be associated with the treatment.