Cancer Research Consortium of West Michigan
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FAST FACTS

Study Title for Study Participants:

"TrACER": Trial Assessing CSF prescribing Effectiveness and Risk

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1415CD, "A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk ("TrACER")"

Disease Related Criteria

a. Patients must have a current diagnosis of breast cancer, non-small cell lung cancer, or colorectal cancer. The current diagnosis may be an initial diagnosis or recurrence and/or progression of previously diagnosed disease. Cancer may be metastatic or non-metastatic.

Prior/Concurrent Therapy Criteria

a. Patients must be registered prior to or on the same day as their first cycle of chemotherapy for their current disease and stage (or disease setting). Patients must not have had any systemic therapy (chemotherapy or combination regimens) in the 180 days just prior to registration. Prior biologic therapy, immunotherapy, tyrosine kinase inhibitors, and hormonal therapy are allowed.

b. Patients must be planning to receive one of the study-allowed regimens listed in Appendix 18.1 as their initial treatment for their current disease. Myelosuppressive therapy must follow the standard regimen, although a dose reduction of up to 10% is permitted. This treatment may be neoadjuvant or adjuvant chemotherapy. Patients must not be receiving or planning to receive concurrent radiation during systemic treatment.

c. Patients must not have any known contraindication to CSFs prior to registration, including prior hypersensitivity to Escherichia coli-derived proteins, filgrastim, pegfilgrastim, or tbo-filgrastim.

Clinical Criteria

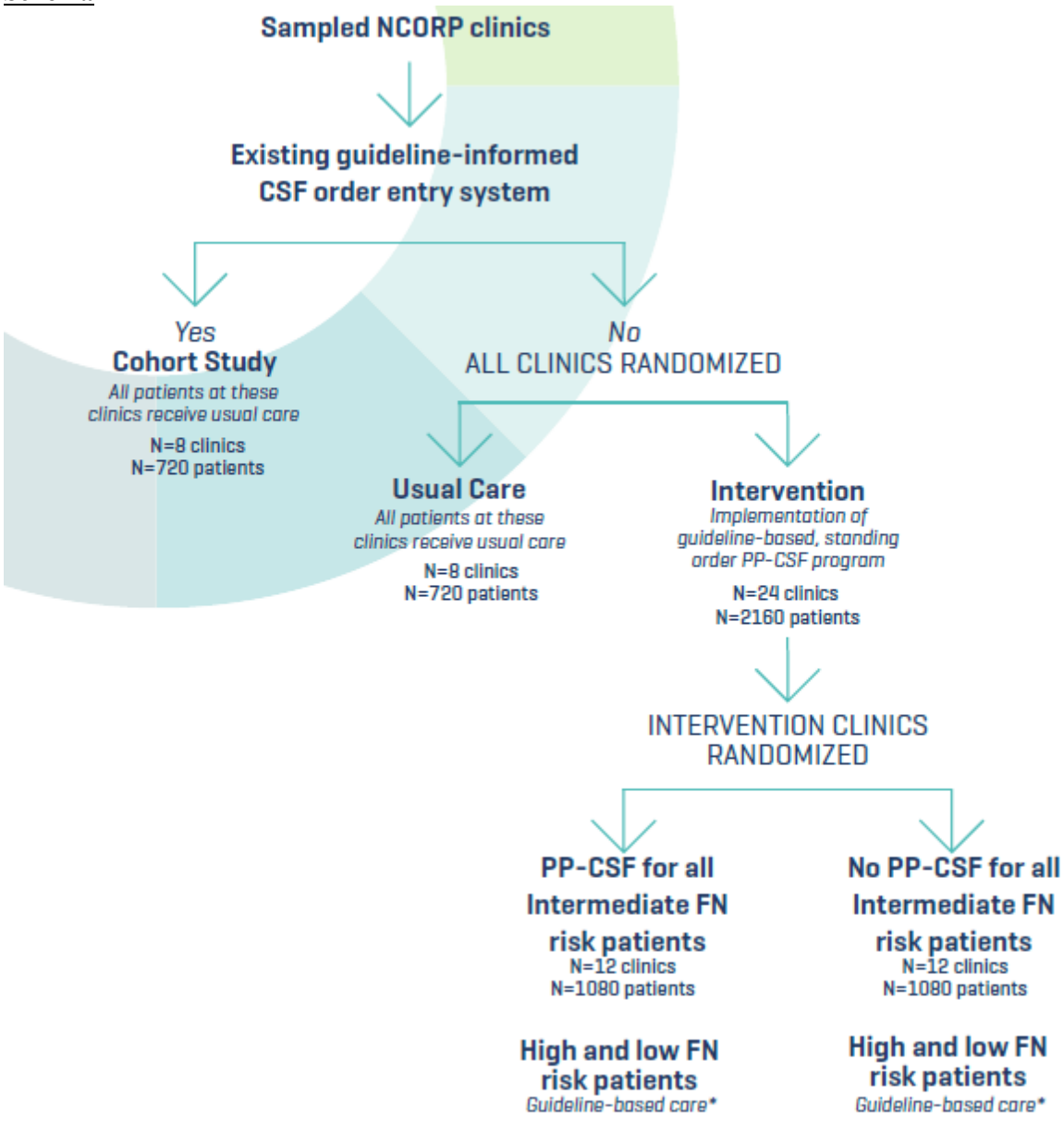
a. Patient must be at least 18 years of age.

b. Patients must be able to understand and provide information for the patient-completed study forms in either English or Spanish.

c. Patients may have had a prior malignancy.

d. Patients must not be participating or plan to participate in other clinical trials that involve investigational systemic cancer treatments or investigational uses of CSF during their first 6 months after registration.

Schema



Pre-study parameters:

- Baseline patient survey
- Medical conditions questionnaire
- FACT –N (version 4)
- Registration Worksheet
- Onstudy Form
- Baseline Laboratory Values Form
- Cover sheet for patient- completed questionaires