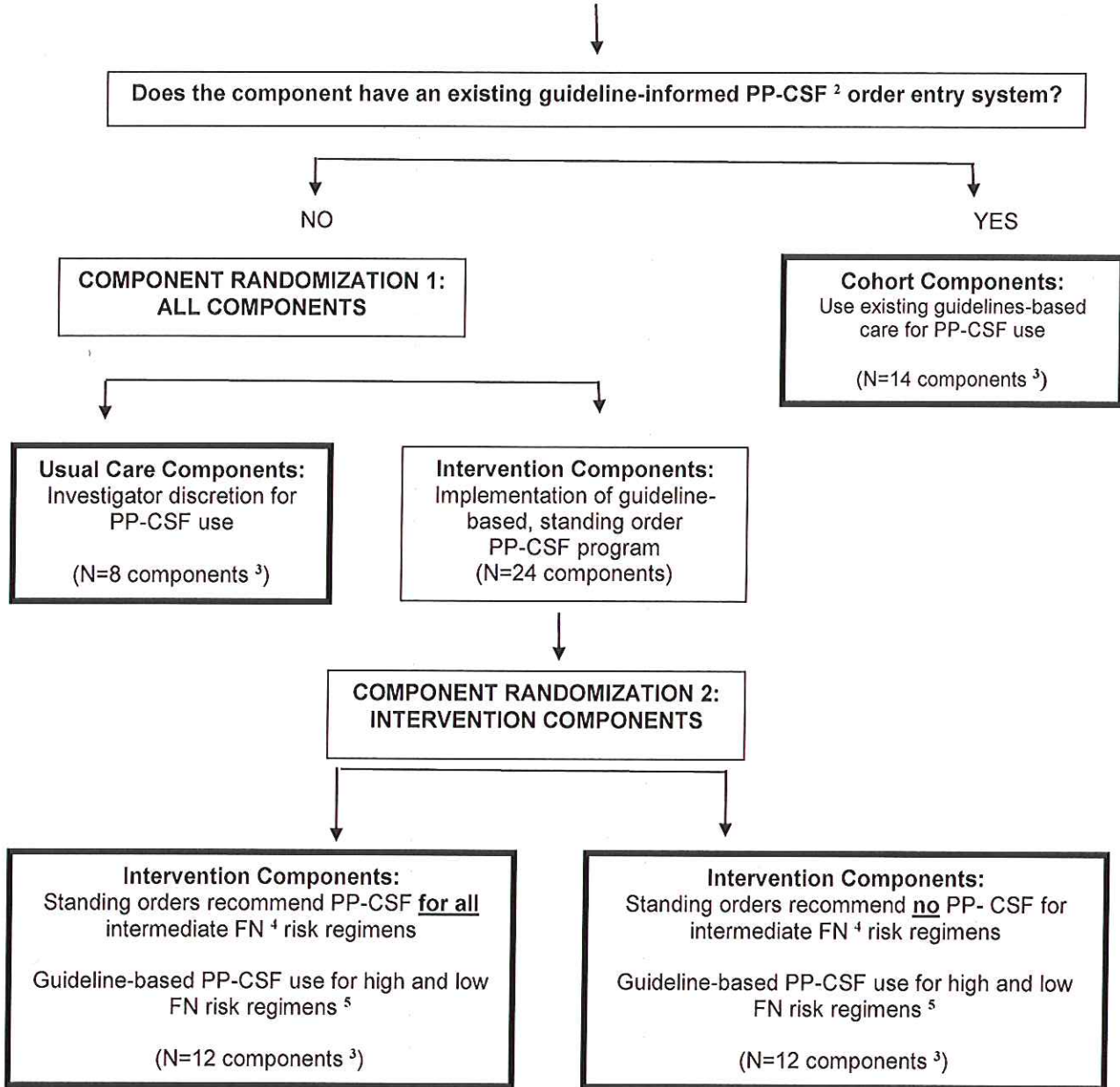


COMPONENT SCHEMA

SWOG, Alliance, NRG and ECOG-ACRIN CCDR NCORP COMPONENTS ¹



¹ Eligible CCDR components must have submitted the S1415CD Component Application and been approved for participation.

² Primary Prophylactic Colony Stimulating Factor.

³ All patients at participating components will be subject to the PP-CSF use care as determined by component assignment (Usual Care, Intervention, or Cohort). Only consented patients registered to the study will participate in the data collection.

⁴ Febrile neutropenia.

⁵ As determined at point-of-care by the guideline-based standing order PP-CSF program (see [Appendix 18.1](#)).

5.0 ELIGIBILITY CRITERIA FOR PATIENTS

Patient eligibility requirements are the same for all participating components, regardless of component treatment assignment (Cohort, Intervention, and Usual Care).

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Use the spaces provided to confirm a patient's eligibility. For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see [Section 14.0](#)). Any potential eligibility issues should be addressed to the Data Operations Center in Seattle at 206/652-2267 prior to registration.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 2 weeks later would be considered Day 14. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 180 falls on a weekend or holiday, the limit may be extended to the next working day.**

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.1 Disease Related Criteria

- _____ a. Patients must have a current diagnosis of breast cancer, non-small cell lung cancer, or colorectal cancer. Cancer may be metastatic or non-metastatic.

5.2 Prior/Concurrent Therapy Criteria

- _____ a. Patients must be planning to receive one of the study-allowed regimens listed in [Appendix 18.1](#) as their initial treatment for their current diagnosis.
- _____ b. Patients must be registered prior to their first cycle of systemic therapy (chemotherapy, immunotherapy, biologic therapy, or combination regimens) for this diagnosis. If patient has had any prior systemic therapy for another malignancy, patient must not have had any systemic therapy in the 180 days just prior to registration.
- _____ 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.

5.3 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.

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.4 Regulatory Criteria

- _____ a. Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

- _____ b. As a part of the OPEN registration process (see [Section 13.0](#) for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.