Cancer Research Consortium of West Michigan
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FAST FACTS

S1714 - A PROSPECTIVE OBSERVATIONAL COHORT STUDY TO DEVELOP A PREDICTIVE MODEL OF TAXANE-INDUCED PERIPHERAL NEUROPATHY IN CANCER PATIENTS

ELIGIBILITY CRITERIA

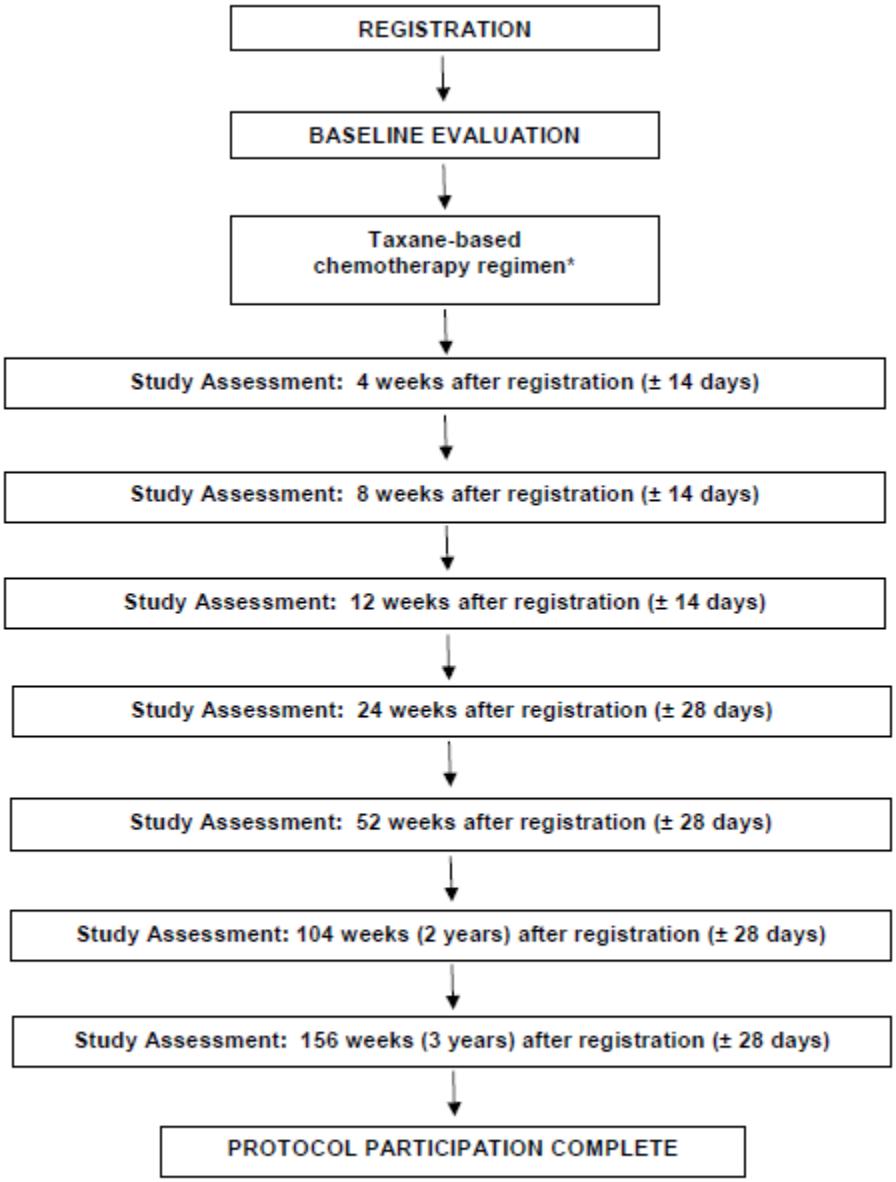
1. Disease Related Criteria
    a. Patients must have Stage I, II, or III primary non-small cell lung, primary breast, or primary ovarian cancer based on clinical or pathologic evaluation. Patients with Stage IV disease are not eligible.

2. Prior/Concurrent Therapy Criteria
    a. Patients must be planning to start treatment with a taxane-based chemotherapy as part of one of the study-approved taxane regimens (docetaxel chemotherapy regimens for treatment of breast or ovarian/fallopian tube cancer, or paclitaxel chemotherapy regimens for treatment of breast, non-small cell lung, or ovarian/fallopian tube cancer) within 14 days after registration. (Note that carboplatin is allowed only as described in Appendix 18.1. However, any of the regimens in Appendix 18.1 may be combined with a non-neurotoxic chemotherapy, such as cyclophosphamide, and/or a biologic agent, such as trastuzumab. Permitted biologic agents include, but are not limited to, pembrolizumab, bevacizumab, trastuzumab, or pertuzumab. Nab-paclitaxel may **not** be substituted for paclitaxel for purposes of this study.) See Appendix 18.1 for the study-approved docetaxel and paclitaxel-based regimens.
    b. Patients who will receive treatment in the setting of any other clinical trial are eligible as long as it is one of the study-approved regimens listed in Appendix 18.1. Patients may receive additional treatments (i.e., experimental therapy, immunotherapy, biologics, etc.) as part of another clinical trial in addition to any regimen approved in this study.
    c. Patients must not have received a taxane (paclitaxel, docetaxel, or protein-bound paclitaxel), platinum (cisplatin, carboplatin, or oxaliplatin), vinca alkaloid (vinblastine, vincristine, or vinorelbine), or bortezomib-based chemotherapy regimen prior to registration. (Note that while patients must not have received carboplatin in the past, patients may receive a carboplatin-containing regimen after registration as part of the docetaxel or paclitaxel regimen.)

3. Clinical/Laboratory Criteria
    a. Patients must be ≥ 18 years of age.
    b. Patients must be able to complete Patient-Reported Outcome (PRO) instruments in English or Spanish. Patients must: 1) agree to complete PROs at all scheduled assessments; and 2) complete the baseline PRO forms prior to registration as outlined in Section 7.5.
    c. Patients with pre-existing neuropathy are eligible, including those with diabetes and neurological conditions such as multiple sclerosis or Parkinson's disease.

4. Specimen Submission Criteria
    a. Patients must agree to submit required specimens for defined translational medicine as outlined in Section 15.1.
    b. Patients must be offered the opportunity to submit additional optional specimens for future, unspecified translational medicine and banking. With patient's consent, specimens must be submitted as outlined in Section 15.1.

SCHEMA



* Can be administered with a non-neurotoxic chemotherapy, such as cyclophosphamide, and/or biologic agents, such as trastuzumab, and/or carboplatin.