Cancer Research Consortium of West Michigan
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FAST FACTS

S2013: IMMUNE CHECKPOINT INHIBITOR TOXICITY (I-CHECKIT)

A PROSPECTIVE OBSERVATIONAL STUDY

5.1 Disease Related Criteria

a. Participants must be planning to receive ICI-based therapy or chemo-ICI for a solid tumor malignancy. This therapy must be given according to NCCN guidelines at Category 1 or 2A and not in the context of a clinical trial. See Section 18.1 for the list of ICI drugs and for the list of specific chemo-ICI regimens permitted in this clinical study.

   NOTE: Patients receiving ICI-based chemo-ICI are eligible if they have one of the following malignancies and are being treated with one of the listed regimens in the advanced disease or neoadjuvant setting (Section 18.1):
   - Small cell or non-small cell lung cancer
   - Gastroesophageal cancer
   - Triple negative breast cancer

   NOTE: Cohort 1 (ICI alone) has been closed to accrual effective 05/06/2024

5.2 Prior/Concurrent Therapy Criteria

a. Participants who have received prior ICI-based therapy must have completed ICI-based therapy at least 180 days prior to registration.
b. Participants must not have discontinued any prior ICI-based therapy (if applicable) because of irAE. S2013 Page 17 Version Date 09/09/2024
c. Participants must not have received chemotherapy, biologic, or targeted-therapy within 14 days prior to registration. Hormonal therapy is allowed.
d. Participants must have recovered from side effects of prior therapy to the following standards per treating physician's discretion:
   - < = Grade 1 for any non-hematologic side effects (excluding neuropathy and alopecia); lab-related parameters of liver and renal function will be considered at the discretion of the treating physician)
   - < = Grade 2 for neuropathy and/or alopecia
   - Grade 3 or less for any hematologic side effects
e. Participants must be planning to begin standard of care ICI-based therapy or one of the chemo-ICI regimens listed in Section 18.1 within 7 calendar days after registration.
f. Participants in the Cohort 1 (ICI-alone) must not be planning to receive ICI-based therapy in combination with chemotherapy or any other non-ICI therapy for treatment of their cancer. Palliative radiation is allowed. NOTE: Cohort 1 (ICI alone) has been closed to accrual effective 05/06/2024 per the SWOG Broadcast.
g. Participants in the Cohort 2 (chemo-ICI) must not be planning to receive any targeted or non-ICI biologic therapy for treatment of their cancer.

h. Participants may receive palliative radiation, growth factor support and osteoclast inhibitor therapy per treating physician's discretion in both cohorts.

5.3 Clinical/Laboratory Criteria

a. Participants must be at least 18 years of age.
b. Participants must complete their history and physical examination within 28 days prior to registration.
c. Participants must be able to complete Patient-Reported Outcome (PRO) instruments in English, Spanish, or French (as applicable) and must be planning to complete these PROs at all scheduled assessments.
   NOTE: The DSQ is only applicable to participants enrolled after the release and implementation of Revision #5 (Version Date 11/1/2023).
d. Participants must complete the pre-registration (baseline) PRO forms within 14 days prior to registration.
e. Participants must be willing to participate in PRO data collection.
   NOTE: Prior to registration, participants must decide on their method (paper or electronic) of completing their follow-up questionnaires. Participants who elect electronic (ePRO) completion must have an iPhone, Android phone, or tablet with cellular or Wi-Fi connectivity in order to download the Patient Cloud mobile applications onto the device (personal device or a site provisioned device for multi-users).
   NOTE: The order of events for the pre-registration PROs is as follows:
   1. Participant signs consent
   2. Administer paper version of PROs
   3. Registration to study
   4. Collection of standard of care laboratory tests and the blood for banking*
   5. Administration of ICI-based therapy or chemo-ICI

   * May also be collected prior to registration

5.4 Specimen Submission Criteria

a. Participants registered by sites located in the United States must be offered the opportunity to participate in the optional specimen banking as outlined in Section 15.2. With participant consent, specimens must be collected and submitted as outlined in Section 15.1.
b. Participants registered by sites located outside of the US must be offered the opportunity to participate in the optional plasma and buffy coat specimen banking collection as outlined in Section 15.2. With participant consent, plasma and buffy coat specimens must be collected and submitted as outlined in Section 15.1.
   NOTE: The optional whole blood and stool collection is limited to participants at US sites only. The optional stool collection is available only to participants enrolled after the release and implementation of Revision #3 (Version Date 3/30/2023).

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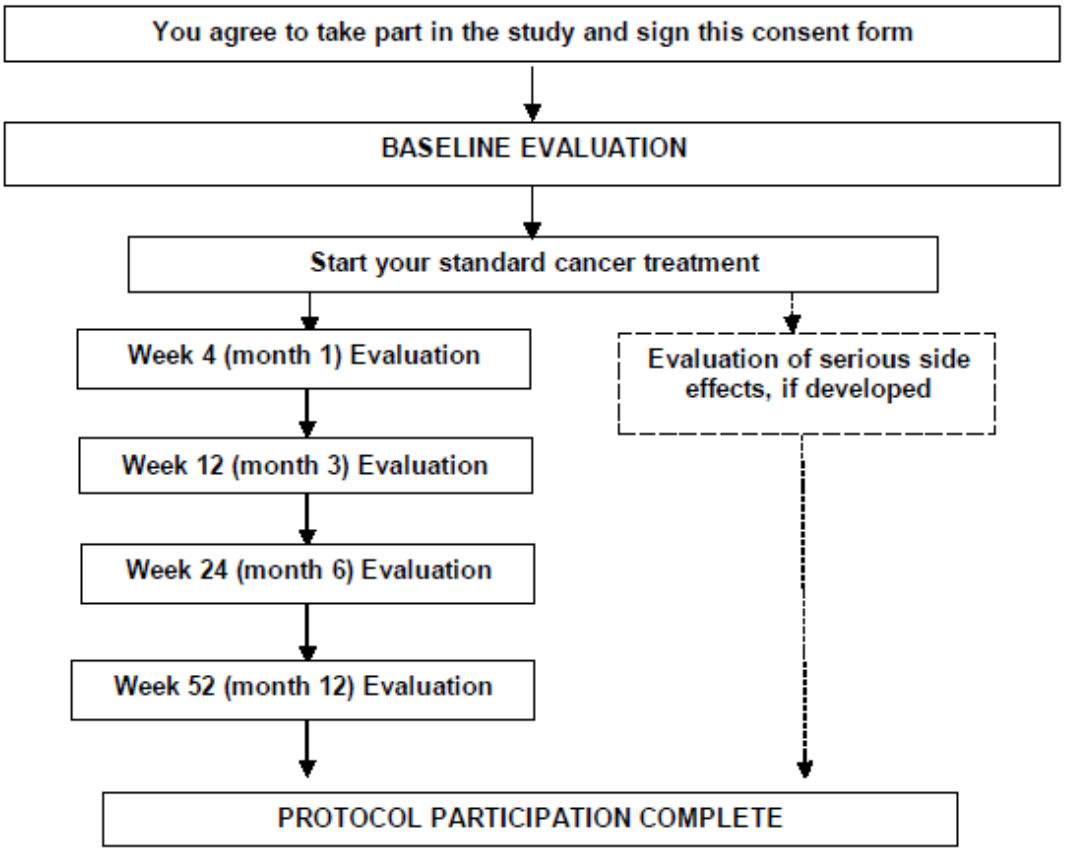
You agree to take part in the study and sign this consent form
BASELINE EVALUATION
Start your standard cancer treatment
Week 4 (month 1) Evaluation
Week 12 (month 3) Evaluation
Week 24 (month 6) Evaluation
Week 52 (month 12) Evaluation
Evaluation of serious side effects, if developed
PROTOCOL PARTICIPATION COMPLETE