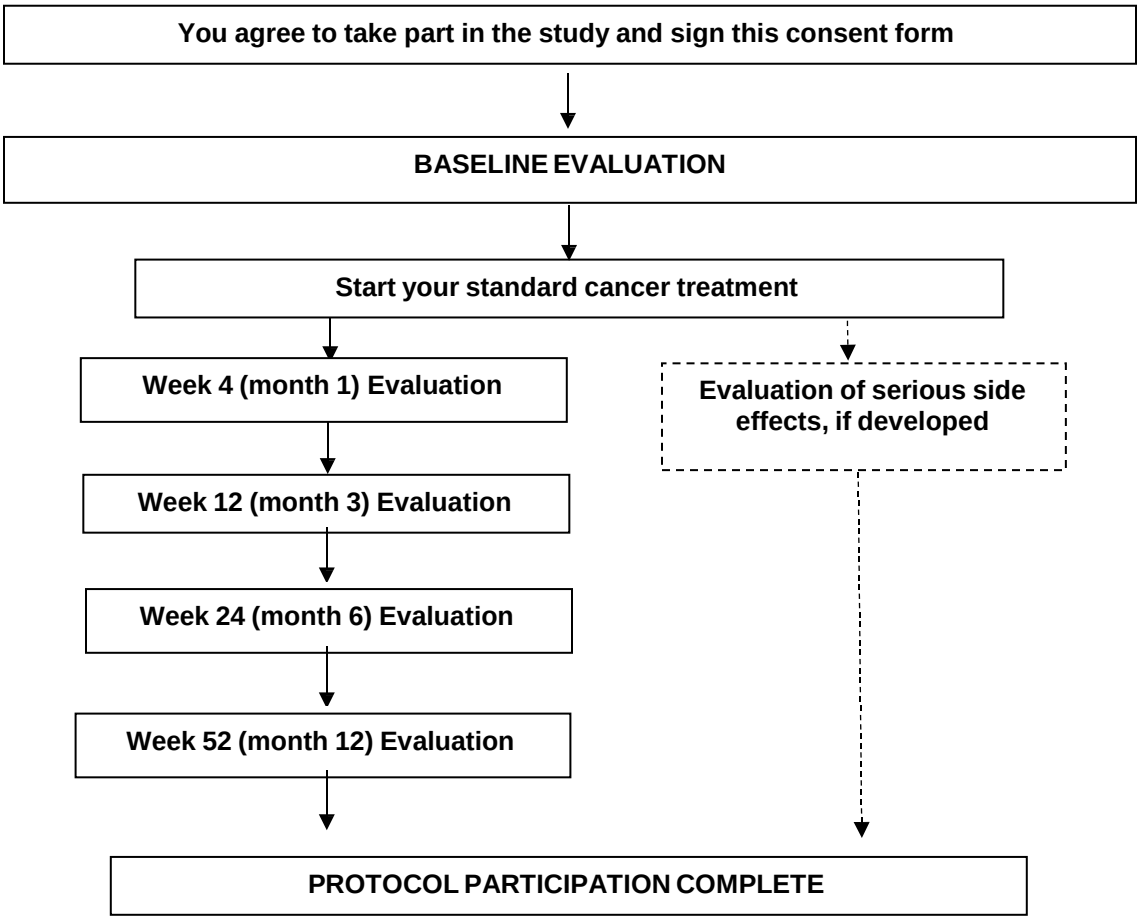
SCHEMA


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

ELIGIBILITY:

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 4 weeks later would be considered Day 28. This allows for efficient participant scheduling without exceeding the guidelines. **If any of the days mentioned in Section 5 falls on a weekend or holiday, the limit may be extended to the next working day.**

5.1 Disease Related Criteria

a. Participants must be planning to receive ICI-based therapy for a solid tumor malignancy. This therapy must be given according to FDA label or NCCN guidelines at Category 1 or 2A and not in the context of a clinical trial. See Section 18.1 for ICI-based therapies.

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.

c. Participants must not have received chemotherapy, biologic, or targeted-therapy within 21 days prior to registration.

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 within 3 calendar days after registration.

f. Participants must not be planning to receive ICI-based therapy in combination with chemotherapy or any other non-ICI therapy for treatment of their cancer.

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 who can complete the **S2013** Feasibility Questionnaire in English or Spanish must participate at the scheduled assessments.

d. Participants must be able to complete Patient-Reported Outcome (PRO) instruments in English, Spanish, or French and must be planning to complete PROs at all scheduled assessments.

e. Participants must complete the pre-registration (baseline) PRO forms within 14 days prior to registration.

f. 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 WiFi connectivity in order to download the Patient Cloud mobile applications onto the device (personal device or a site provisioned device for multi-users).

5.4 Specimen Submission Criteria

a. Participants 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

5.5 Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 13.5 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.

a. Participants ***must*** be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines.

6.0 STRATIFICATION FACTORS

Participants will be classified at registration by planned ICI regimen: single-agent ICI therapy vs combination ICI.