Cancer Research Consortium of West Michigan
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FAST FACTS

ALLIANCE A212102 - BLINDED REFERENCE SET FOR MULTICANCER EARLY DETECTION BLOOD TESTS

Eligibility Criteria for Participants <u>with</u> a Cancer Diagnosis

1. Documentation of Disease:
    a. Histologic Documentation: Histologically confirmed diagnosis of invasive cancer
        - Stage: Stage I-IV per AJCC 7th edition, with the exception of patients with leukemia, lymphoma, and multiple myeloma.
            - For leukemia: Type (CLL, CML, ALL, AML)
            - For lymphoma (any type): Stage I-IV based on Ann Arbor staging
            - For multiple myeloma: Stage I, II, III based on Revised International Staging System (RISS)

    b. One of the following tumor types (synchronous cancers are not allowed and all neuroendocrine tumors are excluded):
        - Colorectal
        - Bladder
        - Head and Neck
        - Hepatobiliary*
        - Lung
        - Lymphoma
        - Leukemia
        - Ovary*
        - Pancreas*
        - Multiple Myeloma
        - Gastric, esophageal or gastroesophageal
        - Breast
        - Kidney*
        - Endometrium*
        - Prostate

        *For these specific cancer types only, patients may be enrolled prior to histologic confirmation of malignancy. Sites are required to contact the Study Chairs to review appropriateness for enrollment. See Section 4.3.2. Eligibility criteria for these patients are listed in Section 3.4.
2. No prior definitive systemic or local anti-cancer intervention (including surgical excision).
3. Age ≥ 40 and ≤ 75
4. No known current pregnancy by self-report
5. No known or prior history of in situ or invasive malignancy other than the current cancer diagnosis. Non-melanoma skin cancers (such as basal or squamous cell) are allowed.
6. Willingness to provide blood samples for research use.
7. Absence of medical contraindications to a research blood draw volume of 60mL
8. No history of organ transplantation
9. Ability to read and comprehend English or Spanish
   Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.

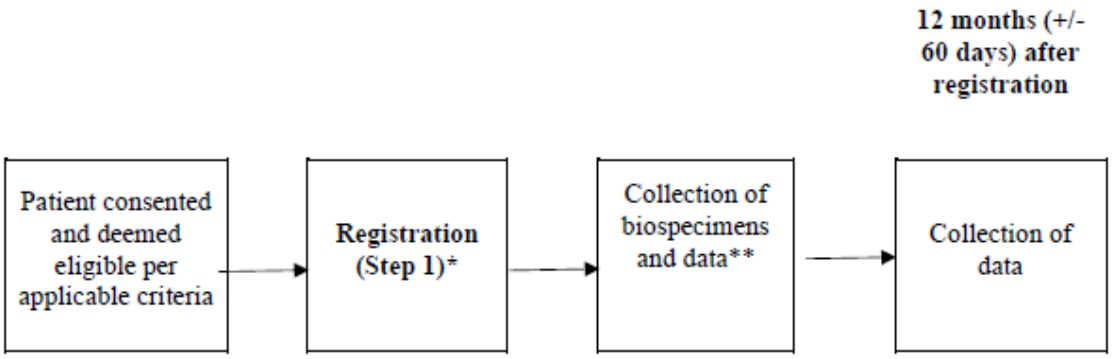
Eligibility Criteria for Participants without a Cancer Diagnosis and without Suspicion of Cancer

1. Age ≥ 40 and ≤ 75
2. No known current pregnancy by self-report
3. No known or prior history of in situ or invasive malignancy Non-melanoma skin cancers (such as basal or squamous cell) are allowed.
4. Willingness to provide blood samples for research use
5. Absence of medical contraindications to a research blood draw volume of 60mL
6. No history of organ transplantation
7. Ability to read and comprehend English or Spanish
   Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.

Eligibility Criteria for Participants with a High Suspicion of Cancer

1. High suspicion of ovarian cancer, pancreatic cancer, kidney cancer, hepatobiliary cancer, endometrial cancer, or melanoma by clinical and/or radiological assessment, with plans for histologic or cytologic confirmation within 28 days after study blood draw.
   - Examples of highly suspicious cases include: elevated CA125 and abnormal transvaginal ultrasound, suspicious renal or pancreatic mass on imaging, suspicious cutaneous lesion concerning for melanoma.
2. Central review of radiology reports and/or clinical documentation conducted by Study Chairs (see Section 4.3.2).
3. Age ≥ 40 and ≤ 75
4. No known current pregnancy by self-report
5. No known or prior history of in situ or invasive malignancy. Non-melanoma skin cancers (such as basal or squamous cell) are allowed.
6. Willingness to provide blood samples for research use
7. Absence of medical contraindications to a research blood draw volume of 60mL
8. No history of organ transplantation
9. Ability to read and comprehend English or Spanish
   Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.

Schema



* Slot reservation required (see Section 4.3).

** For patients with a cancer diagnosis, biospecimens and data should be collected prior to any definitive therapy for the cancer.

Please refer to the full protocol text for a complete description of the eligibility criteria.