Alliance A212102: Blinded Reference Set for Multicancer Detection Blood Tests

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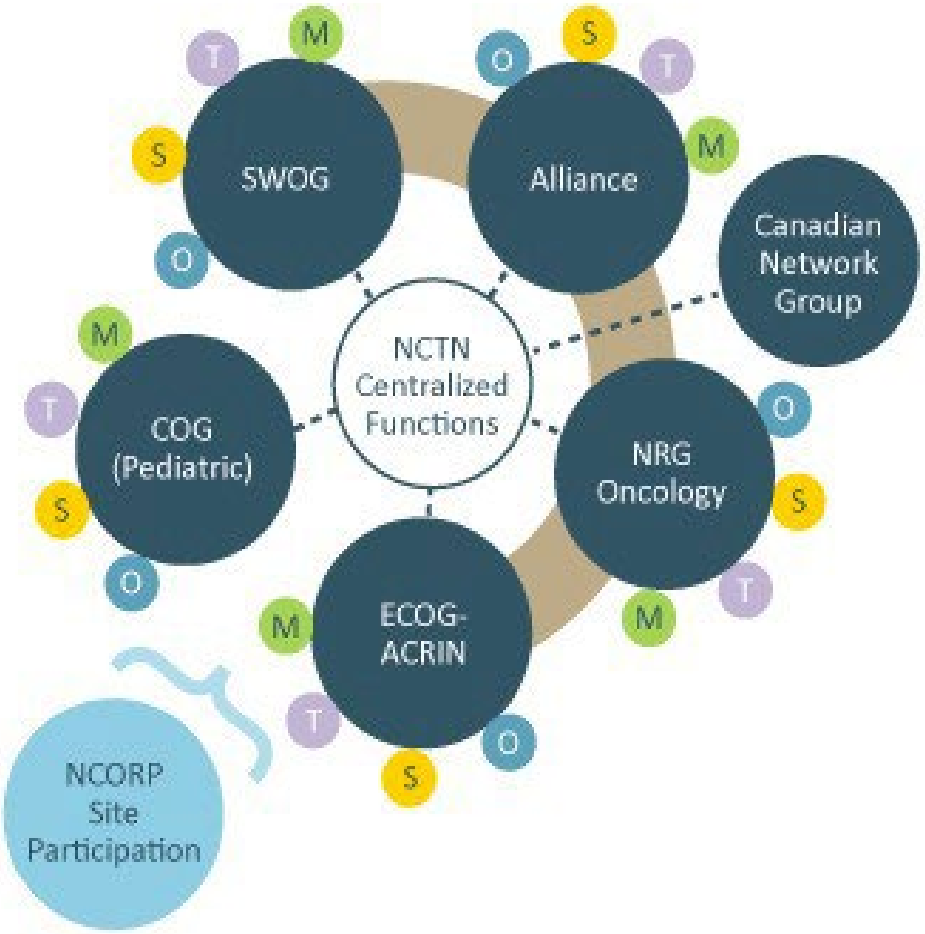
NCI National Clinical Trials Network Structure



LEGEND

- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 30 Lead Academic Participating Sites (LAPS)
- O — Operations
- S — Statistics & Data Management
- T — Tissue Banks
- M — Member Sites

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Alliance for Clinical Trials in Oncology

- Consists of nearly 10,000 cancer specialists at approximately 600 hospitals, medical centers, and community sites across the United States and Canada
- Dedicated to developing and conducting clinical trials with promising new cancer therapies, and utilizes the best science to develop optimal treatment and prevention strategies for cancer, as well as researching methods to alleviate side effects of cancer and cancer treatments

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Alliance Research Pipeline: Productivity 2014-2022

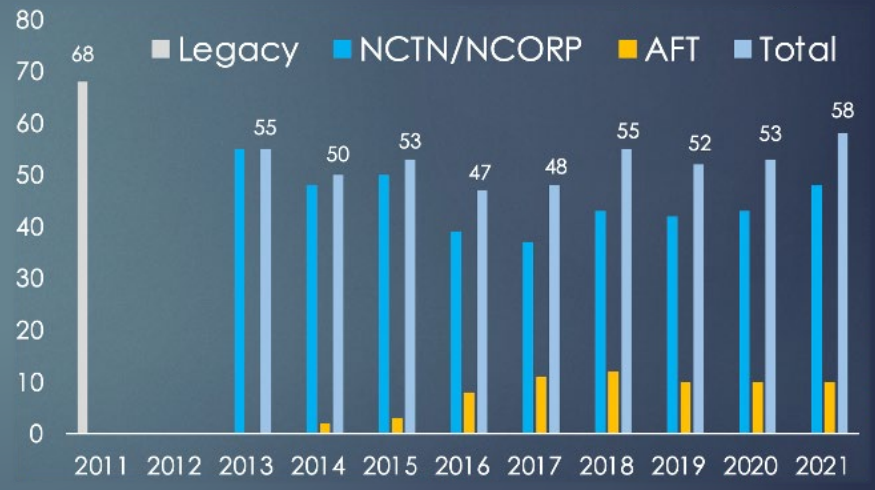
Average per year:

New studies activated **14**

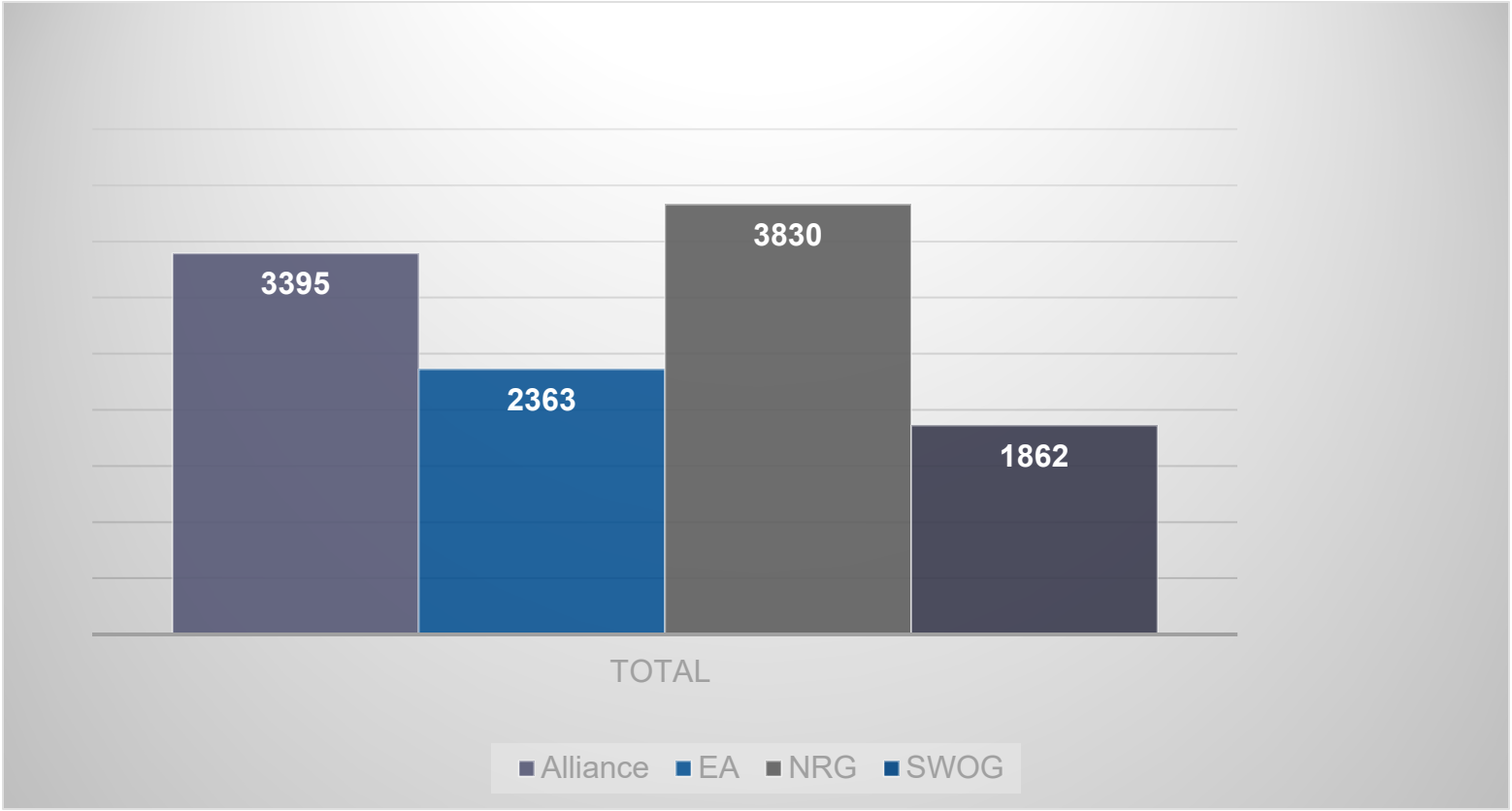
Enrolling trials **53**

67 Manuscripts Published

Enrolling Trials



Patient Accruals: Sept 2021- Aug 2022



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NCI/DCP and Alliance Partnership

- NCI/DCP asked the cooperative groups to consider issues around design of a definitive trial to establish clinical utility
- Alliance sponsored a series “Think Tanks” designed to understand issues around definitive trial
  - What population
  - Endpoints
  - Study Design

- DCP/NCI asked for development of a reference set of cases/controls for assay verification prior to “entry” into definitive trial of clinical utility.

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A212102:
A Blinded Reference Set for Multicancer Early Detection Blood Tests

- Primary Objective
  - To provide a blinded reference set of cancer and non-cancer blood samples to be used to verify performance of MCED assays to be utilized in a prospective trial focused on defining utility of MCED assays.

- Secondary Objectives
  - Evaluate test performance at the time of cancer diagnosis by tumor type
  - Evaluate test performance at the time of cancer diagnosis by clinical stage

- Sample Size
  - 1000 cases and 1000 controls

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Amendment 1: Expansion

- Expanding by 1000 to achieve 30% accrual of under-represented groups.
- Clarifications
  - Eligibility criteria (e.g., surgery counting as prior definitive cancer intervention)
  - Timing of the baseline blood draw
- Submitted to DCP 4/11/2023

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A212102:
Populations to be studied

- Patients with newly diagnosed cancer
- Patients with high suspicion of cancer
- Patients without cancer (healthy control population)

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A212102 Eligibility: Patients with known cancer

- Histologically confirmed diagnosis
- Specific tumor sites
- No prior treatment (including surgery)
- Age ≥40 and ≤75
- No prior history of *in situ* or invasive cancer other than non-melanoma skin cancer
- No prior organ transplant
- Ability to read/comprehend English or Spanish

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Eligible Tumor Sites

- Colorectal
- Bladder
- Head & Neck
- Hepatobiliary
- Lung
- Lymphoma
- Leukemia
- Ovary
- Pancreas
- Myeloma
- Esophageal/Gastric
- Breast
- Thyroid
- Kidney
- Endometrium
- Prostate
- Melanoma
- Sarcoma

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A212102 Eligibility: Patients with high suspicion of cancer

- High suspicion of one of several cancer types:
  - Ovarian, pancreatic, kidney, melanoma
- Planned surgical resection within 28 days of study
- Documentation (i.e., radiology reports) available for central review
- Age ≥40 and ≤75
- No prior history of *in situ* or invasive cancer other than non-melanoma skin cancer
- No prior organ transplant
- Ability to read/comprehend English or Spanish

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A212102 Eligibility: Patients without cancer

- Age ≥40 and ≤75
- No prior history of *in situ* or invasive cancer other than non-melanoma skin cancer
- No prior organ transplant
- Ability to read/comprehend English or Spanish

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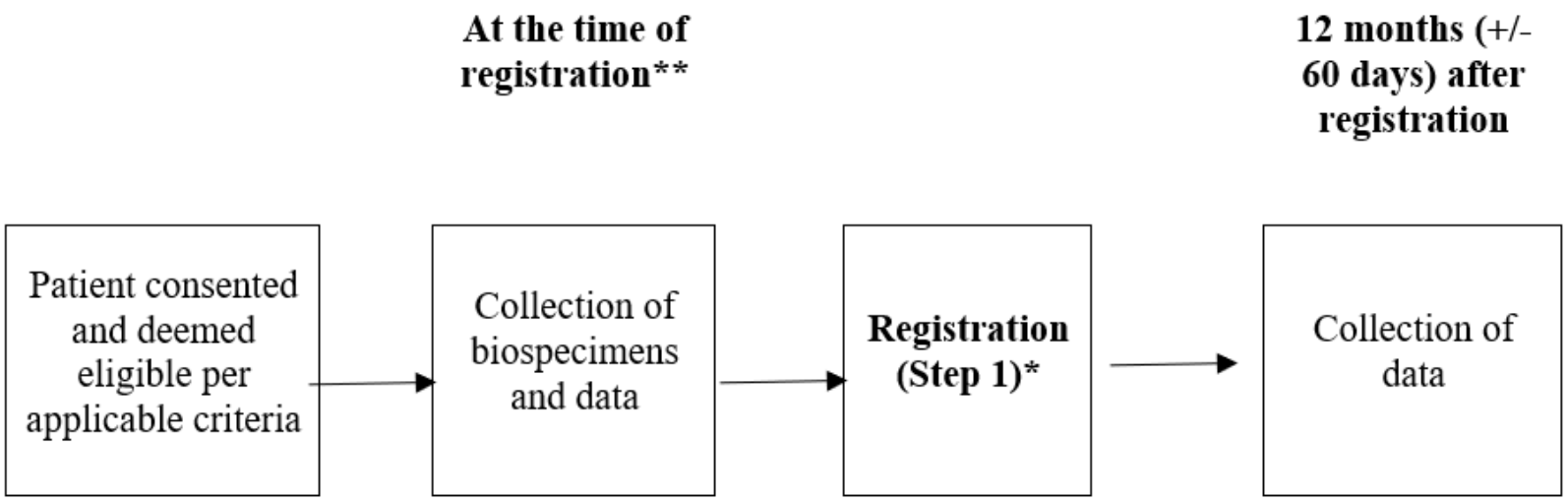
Study Schema



* Slot reservation required

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

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A212102 Eligibility: Data Collection

- Baseline
  - Demographics and Health Information
  - BMI
  - Clinical Staging (for Cancer cases only)
  - Blood
  - Tissue (optional)
- 12 months
  - Update demographic and health information
  - Cancer Status
  - Tissue (optional)
  - Blood (optional)

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A212102: Specimen Submission

	At the time of registration*	12 months (+/- 60 days) after registration
Mandatory for all patients registered to A212102		
Whole blood (Streck tubes)	6 x 10 mL	
For patients consented to biobanking		
Paraffin block	X[1]	
Whole blood (Streck tubes)		6 x 10 mL

* After consent and within 28 days prior to registration. For patients with a cancer diagnosis, biospecimens should be collected prior to starting any definitive therapy for the cancer.

1. Optional (for patients with a cancer diagnosis only). Tissue to be used to obtain reference tumor tissue from cancer patients. In cases where an institution is unable to submit the requested tissue blocks, a representative H&E stained diagnostic slide should be submitted.

A212102: Specimen Submission

- Whole blood collected in 6x Streck BCT tubes and shipped to biorepository to be received within 96 hours of collection.
- Whole blood subjected to double centrifugation.
- 12 x 1.5 ml aliquots of plasma and 2 x buffy coat suspensions created from each patient.
- Stored in LN2 vapor and shipped in batches to FNLCR Biorepository at Frederick on dry ice.
- Processed specimens are stored at -80C in upright, mechanical freezers at the Biorepository

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Patient Engagement Portal (PEP)

- Internet-based program led by Alliance Data Innovation Lab
- Customizable platform:
  - Allows for real time capture of survey data, including self-reported demographics and social determinants of health.
  - Provides study specific updates and can deliver study specific surveys.
- Participant is optional
  - To date 44% of participants have chosen to enroll

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Accrual Demographics

Age	40-49 50-59 60-69	23.91% 29.5% 46.5%
Sex	Male Female,	34.7% 65.3%
Race	White African American Hispanic Other (Asian, NA, UNK, >1)	84.9% 9.0% 5.2% 6.0%

Activated 8/1/2022
Total Accrual as of 5/1/2023: 1539
Controls 1025, Cases 514

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