

NCCAPS: NCI COVID-19 and Cancer Patients Study

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Today's talk

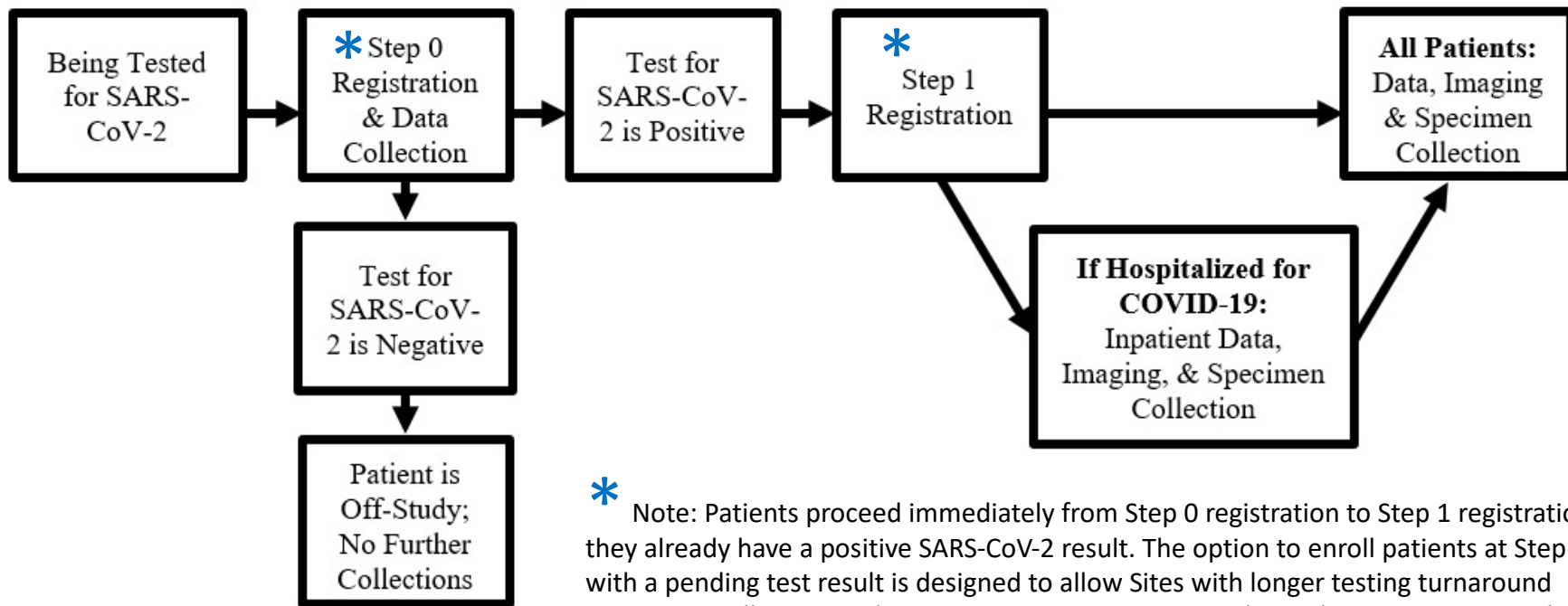
- Background of NCI's COVID-19 and Cancer Patient Study (NCCAPS)
- Describe role of the advocate in NCCAPS
- Discuss what we hope to learn from NCCAPS
- Present early findings of NCCAPS

NCCAPS Objectives: Longitudinal Study

- **Characterize patient factors associated with short- and long-term outcomes of COVID-19** in adult and pediatric cancer patients undergoing active treatment
 - pre-existing comorbidities
 - cancer type and treatment
 - demographic factors
- **Describe cancer treatment modifications** made in response to COVID-19
 - dose adjustments
 - changes in symptom management
 - temporary or permanent cessation.

NCCAPS Schema

- Step 1 Planned Accrual: 2,000 patients
- Follow outcomes for up to 2 years



* Note: Patients proceed immediately from Step 0 registration to Step 1 registration if they already have a positive SARS-CoV-2 result. The option to enroll patients at Step 0 with a pending test result is designed to allow Sites with longer testing turnaround times to enroll presumed positive patients. For sites with rapid testing turnaround, or for non-symptomatic patients undergoing routine pre-treatment testing, patients should be enrolled after receiving a positive test result to Step 0 and Step 1 simultaneously.

NCCAPS Study Plan

Collect Data

- Cancer type and treatment
- Demographic factors
- Pre-existing comorbidities
- COVID-19 course, severity
- COVID-19 treatment
- Quality of life

Collect Imaging Scans

- Most recent pre-COVID-19 cancer imaging study
- Imaging studies done as clinically indicated for cancer
- Imaging studies done as clinically indicated for COVID-19

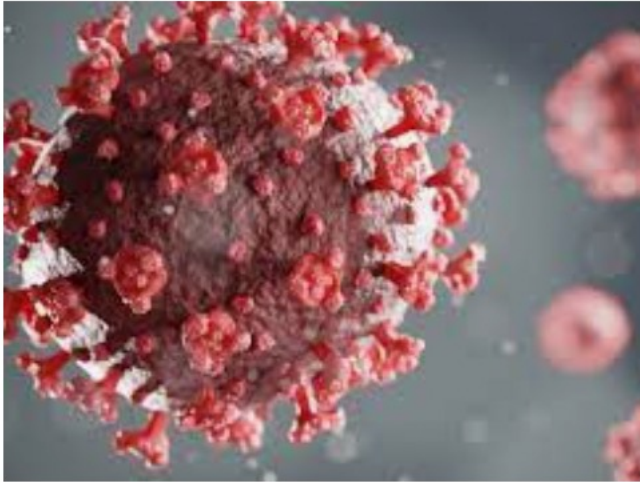
Collect Research Specimens

- Longitudinal biospecimen collection
- Factors associated with severe disease
 - Development of immune response
 - Trajectory of immune response

Role of Advocate in NCCAPS

- Serving as members of study working group from first meeting
- Provided input on study objectives and protocol
- Reviewed and provided input on informed consent and patient communication materials
- Served on correlative sub-study group that developed quality of life objectives

NCCAPS – Current Status



- **Closed to accrual February 2, 2022**
- Small number of patients have completed 2 years of follow-up
- ASCO 2021:
 - Inpatient abstract
 - Outpatient abstract
- ASH 2022: Preliminary results of coagulation studies
- Vaccine severity analysis

NCCAPS Accrual

Screening accruals: 2050

Longitudinal study accrual:
1833

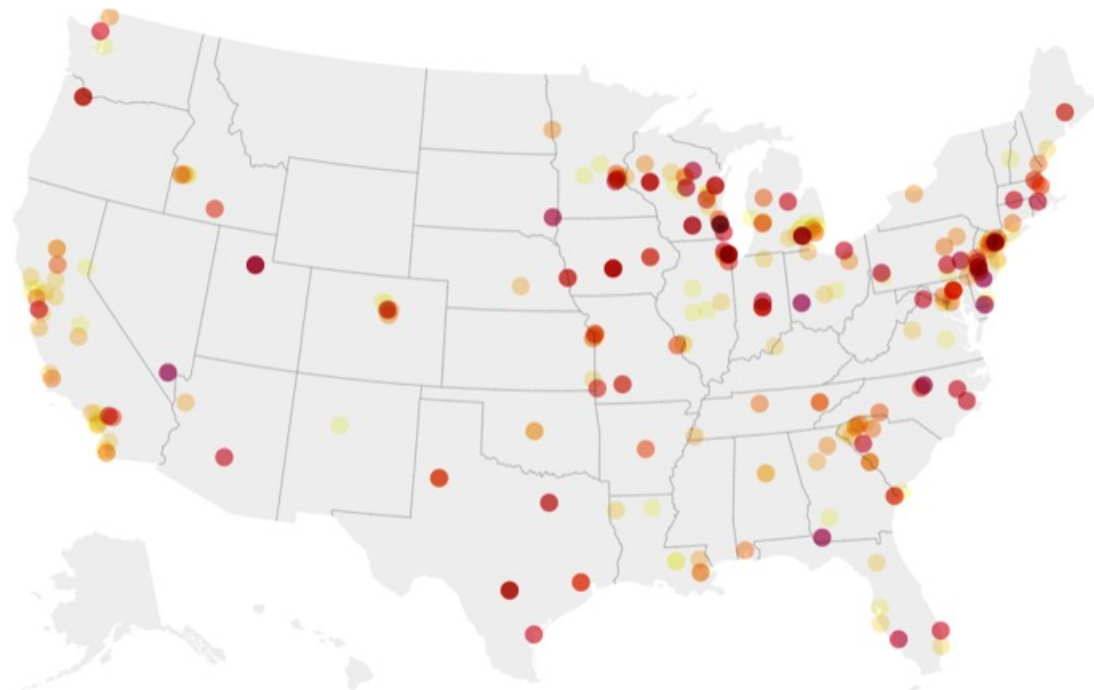
Pediatric: 171

Vaccine sub-study: 70
patients contributed 1 or
more voluntary specimens.

COVNET: 84

NCCAPS Enrolling Sites

Step 1 Patients Enrolled at Site

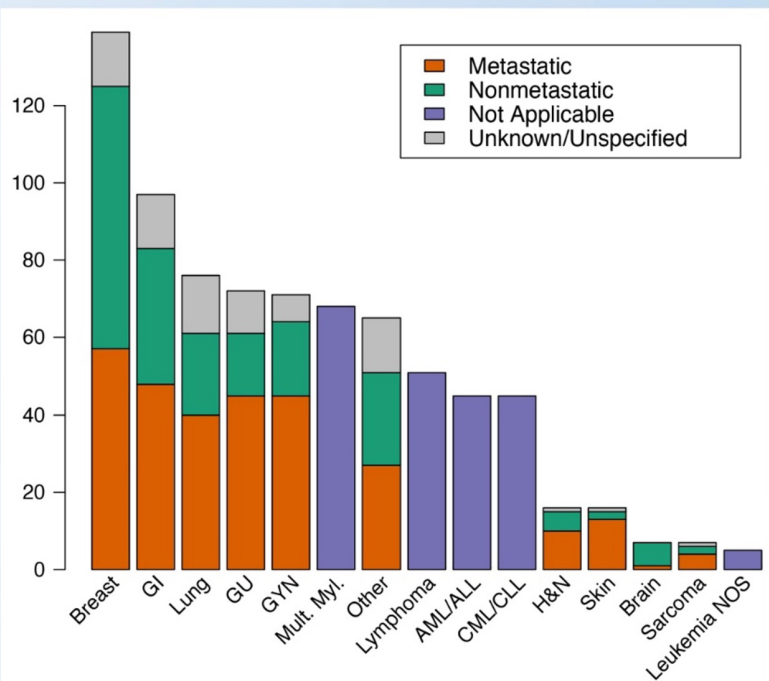


Preliminary Results

Presented at ASCO June 2021

Cancer Diagnosis

Cancer Diagnoses in Adult Patients (N=780)



Cancer Diagnoses in Pediatric Patients (N=47)

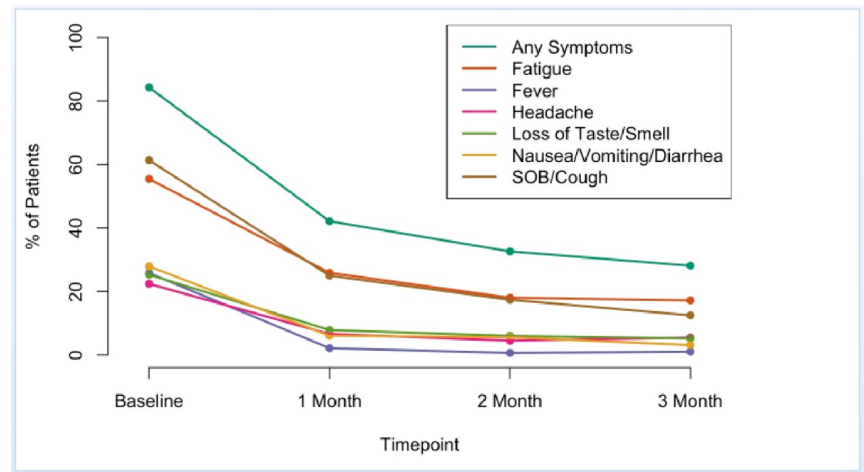
- Acute Leukemia – 66%
- Lymphoma – 8.5%
- Sarcoma – 10.6%
- Brain – 2.1%
- Immature teratoma – 2.1%
- Other – 10.5%

Baseline Comorbidities

Category	% of patients
Current/former smoker	50
Cardiac	47.2
Pulmonary	25
On anticoagulation	21.3
Type II Diabetes	15.7
Renal	13.9
Neurologic	8.3
Hepatic	5.6
Pregnancy	0.9

COVID-19 Symptoms

Symptom	% of patients @ presentation
Fatigue/malaise	47.5
Shortness of breath	30.3
Dry cough	27.9
Fever	28.7
Productive cough	21.3
Headache	18.9
Myalgia	18.9
Loss of taste	18
Diarrhea	17.2



Patient Outcomes

- Among 780 adult patients ≥ 30 days from COVID test date, all-cause mortality was 9.7%:
 - 25 (3.2%) died of COVID-19
 - 33 (4.2%) died of cancer
 - 18 (2.3%) died of other causes
- 166 pts (162 adult, 4 pediatric) were hospitalized for COVID-19; 31 had multiple COVID-19 related hospitalizations
- Among 47 pediatric patients ≥ 30 days from COVID test date, there was one death from malignancy and no deaths from COVID-19

Future Directions

- Initial outcomes for full study sample
- Severity of COVID-19 by vaccination status
- Ongoing correlative analyses:
 - Cytokine profiles
 - Immune cell phenotyping
 - Serology/neutralizing antibodies
- Long COVID assessment
- Pediatric population
- Imaging findings





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