

FAST FACTS

NCI COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study

Eligibility Criteria

1. Step 0 Eligibility Criteria

- a. No age restriction
- b. Patient must have a prior or current cancer diagnosis (e.g., solid tumor or hematologic malignancy) that fits into any one of the following categories:
 - i. Patient is receiving active treatment (defined as current treatment or treatment within the past 6 weeks) or will begin receiving treatment within the next 2 weeks for any CNS or hematologic malignancy or metastatic (Stage IV) solid tumor. Eligible treatment types for hematologic malignancy or metastatic cancer are chemotherapy, immunotherapy, monoclonal antibody therapy (e.g., rituximab, trastuzumab, cetuximab), targeted therapy (e.g., BRAF/MEK inhibitor, EGF-R inhibitor), endocrine therapy, radiation therapy, or targeted radionuclide therapy; or
 - ii. Patient is receiving treatment (defined as current treatment or treatment within the past 6 weeks) or will begin receiving treatment within the next 2 weeks for non-metastatic (Stage I-III) solid tumor. Eligible treatment types for non-metastatic cancer patients are intravenous chemotherapy, immunotherapy, targeted therapy, radiation therapy, targeted radionuclide therapy, or monoclonal antibody therapy, except trastuzumab/pertuzumab if not accompanied by chemotherapy; or
 - iii. Patient has received an allogenic stem cell transplant or CAR-T cell or other modified cellular therapy at any time; or
 - iv. Patient is currently receiving treatment or prophylaxis for Graft vs. Host Disease; or
 - v. Patient has received an autologous bone marrow transplant within the past 2 years.
- c. Testing for SARS - CoV-2
 - i. Patient must be undergoing or have undergone viral testing for SARS CoV-2.

Patients with prior negative viral SARS CoV-2 test(s) are eligible if they are being tested again.

Patients 18 years of age and older with prior positive viral SARS - CoV-2 test(s) more than 14 days prior to enrollment to step 1 are not eligible.
- d. HIV-infected patients are eligible
- e. Patients with CNS metastases are eligible
- f. Co-enrollment on other clinical trials (for cancer or for COVID-19) is allowed.

2. Step 1 Eligibility Criteria

- a. Positive viral SARS - CoV-2 test

Patient must have a documented positive viral SARS CoV-2 test.

- For patients 18 years of age or older, the specimen collection for the positive test must have occurred no earlier than 14 days prior to enrollment to Step 1.
- For patients under 18 years of age, the specimen collection for the positive test must have occurred after January 31, 2020.

The test must have been performed at a CLIA certified laboratory.

The viral test can be either a nucleic acid (PCR) test or an antigen test. Serological or antibody tests are not allowed.

The specimen must have been collected at a SARS-CoV-2 testing site such as a doctor's office, hospital, clinic, pharmacy, or drive-through testing site. Positive test results from home collection kits are not allowed.

Any specimen source (e.g., nasopharyngeal swab, oropharyngeal swab, etc.) is allowable for the viral SARS-CoV-2 test.

SCHEMA

