Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

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

Eligibility Criteria

a. Patient must have a prior or current cancer diagnosis (e.g., solid tumor or hematologic malignancy) and cancer treatment that fits into one of the three following categories:
    i. Metastatic (Stage IV) solid tumor, any hematologic malignancy, or any CNS malignancy, and:
        1. Patient is receiving eligible active treatment (defined as current treatment or treatment within the 6 weeks prior to their first positive SARS-CoV-2 test collection) or is expected to begin receiving treatment within 2 weeks of study enrollment.
        2. Eligible active treatment types 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.
    ii. Non-metastatic (Stage I-III) solid tumor and:
        1. Patient is receiving eligible active treatment (defined as current treatment or treatment within past 6 weeks prior to their first positive SARS-CoV-2 test collection) or is expected to begin receiving treatment within 2 weeks of study enrollment.
        2. Eligible active treatment types for non-metastatic solid tumor patients are intravenous chemotherapy, immunotherapy, targeted therapy, radiation therapy, targeted radionuclide therapy, or monoclonal antibody therapy (except as noted below).
            a. HER2-targeted therapy (trastuzumab, pertuzumab, neratinib, adotrastuzumab) that is not accompanied by chemotherapy is NOT considered an eligible active treatment
            b. Patients on endocrine therapy alone are not eligible.
    iii. Prior or current transplant for the treatment of cancer:
        1. Patient has received an allogenic stem cell/bone marrow transplant or CAR-T cell or other modified cellular therapy at any time; or
        2. Patient is currently receiving treatment or prophylaxis for Graft vs. Host Disease; or
        3. Patient has received an autologous stem cell/bone marrow transplant within the past 2 years.

b. Patient must have documented positive viral test result for SARS-CoV-2.
    i. For patients 18 years of age or older, the specimen collection for the patient's FIRST positive test must have occurred no earlier than 14 days prior to enrollment.
    ii. For patients under 18 years of age, the specimen collection for the patient's first positive test must have occurred after January 31, 2020. The viral test can be either a nucleic acid (PCR) test or an antigen test. Serological or antibody tests are not allowed. Any specimen source (e.g., nasopharyngeal swab, oropharyngeal swab, etc.) is allowable for the viral SARS-CoV-2 test. Patients with prior negative viral SARS-CoV-2 test(s) are eligible if they are being tested again. The SARS-CoV-2 test must be a validated diagnostic assay performed in accordance with the most recent guidance issued by the FDA in the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. This policy is available at: https://www.fda.gov/regulatory-information/search-fdaguidance-documents/policy-coronavirus-disease-2019-tests-during-public-healthemergency-revised

c. HIV-infected patients are eligible

d. Patients with CNS metastases are eligible.

e. Co-enrollment on other clinical trials (for cancer or for COVID-19) is allowe

Pediatric COVNET Cohort Eligibility Criteria

Patients should only be enrolled in the pediatric COVNET cohort if they are not eligible for the main NCCAPS Study cohort or decline to participate in the main study.

1. Patient must be < 18 years of age
2. Patient must have a positive SARS-CoV-2 viral test after January 31, 2020.
3. Patient must have a current or prior diagnosis of cancer. Active cancer treatment is not required.

*Note: Patients who enroll on Pediatric COVNET cohort will not be followed longitudinally; study data collection involves only a single questionnaire and research blood collection. A separate consent document is provided for the Pediatric COVNET cohort.

NCCAPS Main Study Schema: