

ASCO Survey on COVID-19 in Oncology (ASCO) Registry

Study Schema

Rationale: Why is ASCO Doing This?

The COVID-19 Pandemic presents a unique opportunity to capture information on how a disease outbreak affects delivery of high-quality cancer care. ASCO is poised to provide the means for the oncology community to rapidly submit data that will enable us to inform both current cancer care and provide information to help guide decision-making for future disease outbreaks. While other entities have launched COVID-19 cancer registries, ASCO has extensive relationships with the entire cancer care community, particularly private practices that may be caring for the majority of cancer patients with COVID-19. Similar to other registries, ASCO's registry will collect baseline information about patients with cancer at the time of presentation with confirmed COVID-19 infection based on a positive test. Unlike other registries, ASCO's registry will collect follow-up information on both COVID-19 disease and cancer outcomes.

Project Objectives:

- Capture and analyze current status and eventual outcomes of cancer patients with confirmed COVID-19 from participating cancer practices/institutions for 12 months. Data collected will include treatment approaches, cancer status, changes to cancer evaluation and treatment plans in patients with confirmed SARS-CoV-2 infection, status of COVID-19 infection (e.g., severity of symptoms, need for ventilator, hospitalization, etc.) and cancer (e.g., cancer progression, treatment-related changes/modifications, etc.).

Project Deliverables:

- Web-based Registry
- Periodic Reports on Estimates of Disease Severity, Treatment Modifications, and Clinical Outcomes Among Patients – for participating sites and publicly accessible on ASCO websites for the oncology community
- Manuscript(s) for Submission to Peer-Reviewed Journals

Research Objectives:

Objective 1: Describe the distribution of symptoms and severity of COVID-19 among patients with cancer (on active treatment or on adjuvant treatment within 12 months after surgical resection) who have confirmed infection of SARS-CoV-2

- **Objective 1.1:** Describe distribution of symptoms and severity of COVID-19 stratified according to demographic characteristics, including age, cancer type, cancer stage, distribution across stage in cancer continuum (see below 1-5 of Eligibility Criteria), race, ethnicity, geography, type of therapy received, smoking status, comorbidities, etc.
- **Objective 1.2:** Examine whether any of the characteristics are independently associated with severity of COVID-19.

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Objective 2: Examine SARS-CoV-2 viral infection outcomes (ongoing, recovery, hospitalized, not in ICU; hospitalized in ICU; placed on ventilator; death due to COVID-19 disease complications) and cancer outcomes (stable, response to treatment, progression, delayed treatment, treatment discontinued, and death)

- **Objective 2.1:** Stratify patients with SARS-CoV-2 viral infection according to characteristics described in Objective 1.1 to examine whether any of the characteristics are independently associated with COVID-19 and/or cancer outcomes
- **Objective 2.2:** Examine the relationship between SARS-CoV-2 viral infection outcomes and cancer outcomes and whether SARS-CoV-2 viral infection outcomes are independently associated with cancer outcomes

Objective 3: To describe effects of the COVID-19 pandemic on cancer practices in the U.S., including changes in staffing and resource availability, prioritizations for patient care, and modification of interactions between care providers and patients (including use of telemedicine)

Eligibility Criteria:

The registry will collect data about patients with a cancer diagnosis who have a confirmed SARS-CoV-2 infection and are being treated at participating cancer practices/institutions within the United States.

Cases Included at Launch

1. Patients with a new cancer diagnosis and in the process of cancer staging and/or receipt of initial cancer therapy
2. Patients with clinically evident cancer receiving anti-cancer treatment,
3. Patients who are disease free, but receiving any type of adjuvant therapy within 1 year following surgical resection (including hormonal treatments), and
4. Patients with clinically evident cancer receiving supportive care only.

Cases ASCO Will Consider Adding Later

1. Patients who are continuing adjuvant hormonal therapy alone greater than 1 year following completion of curative therapy
2. Patients who are cancer survivors without evidence of disease, have completed anti-cancer therapy and are in surveillance

Statistical Considerations and Reporting

ASCO's Center for Research and Analytics (CENTRA) will periodically create reports to share with participating practices and the general cancer community. Reports will summarize frequency and severity of COVID-19 infection, COVID-19 interventions in cancer patients, overall and stratified by patient characteristics, such as disease sites and stage, age and comorbidities. Reports will also include cancer treatment delay and discontinuation of cancer treatments including surgery, radiation and drug-based therapies, due to the patient's COVID-19 disease and to other factors, with stratification by other variables as described above. Changes in practices' patterns of care, staffing, resources, and interactions with patients will also be evaluated and summarized.

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ASCO will strive to provide reports at least monthly. However, timing will depend on the number of cases reported to the registry, and the availability of subsequent outcome information. As there is no hypothesis testing planned, there is no required sample size and providing repeated reports, with cumulative information, will not affect validity of results. Confidence intervals will be provided where appropriate to demonstrate precision of estimates.

IRB Review

ASCO received approval from the Western Institutional Review Board (WIRB):

“We determined this study is exempt from IRB review because it does not meet the definition of human subject as defined in 45 CFR 46.102. Specifically this study will [*sic*] deidentified data in the form of limited data sets from the participating clinics and institutions and you will enter into Data Use Agreements, and you will not otherwise interact with the patients.”

The WIRB letter is available on the ASCO Registry website. ASCO encourages practices to rely on the WIRB review. If local IRB approval is necessary, the review must be completed before the practice can execute the data use agreement (DUA) with ASCO.

Practice Expectations *(Refer also to study calendar in Appendix.)*

- Review study schema, data collection elements, and WIRB determination.
- Complete practice contact information (link available at the ASCO Registry website) and download the DUA. In the interest of prompt data reporting, ASCO will only entertain DUA revisions related to the local site contact information.
- Contact CENTRA@ASCO.org to express interest in participation and execute DUA with ASCO.
- Access web address provided by ASCO for data entry and select practice name from the drop-down list of practices that have executed a DUA.
- Complete initial and follow-up data entry forms. Follow-up data includes information on COVID-19 and cancer treatment and outcomes. Ideally, data entry will be done routinely (weekly or monthly). If possible, practices should attempt to obtain information from inpatient hospitalizations.
 - Data includes:
 - Limited patient identifiable data, including home zip code, practice zip code, date of birth, gender, race, ethnicity, type of cancer, and comorbidities
 - COVID-19 status (e.g. symptoms, treatments, and outcomes)
 - Cancer status (e.g., treatment plans, any changes to treatment plans, and response to treatments)
 - ASCO encourages practices to create a local standard operating procedure (SOP) to arrange systematic data entry. Data could be retrieved from the EHR using the new ICD-10-CM diagnosis code U07.1 ([created by the Centers for Disease Control and Prevention \(CDC\) on March 18, 2020](#)). Previous ICD-10-CM codes were 1) Coronavirus, as cause of disease classified elsewhere B97.29, 2) Coronavirus NEC B34.2, and 3) SARS-associated coronavirus J12.81. The coding system for laboratory and clinical test results (LOINC) has also established several [codes for tests for the COVID-19 virus: SARS Coronavirus 2](#).

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- Practices may have to contact the hospital for information regarding an inpatient admission. ASCO plans to provide compensation to participating sites to help cover the costs of entering registry data.

ASCO will list participating practices on the ASCO Registry webpage. Practices may withdraw from the registry at any time.

Please contact CENTRA@ASCO.org for additional information or questions.

Appendix – Study Calendar and Timelines

Study Calendar for Patients in ASCO Survey on COVID-19 in Oncology Registry

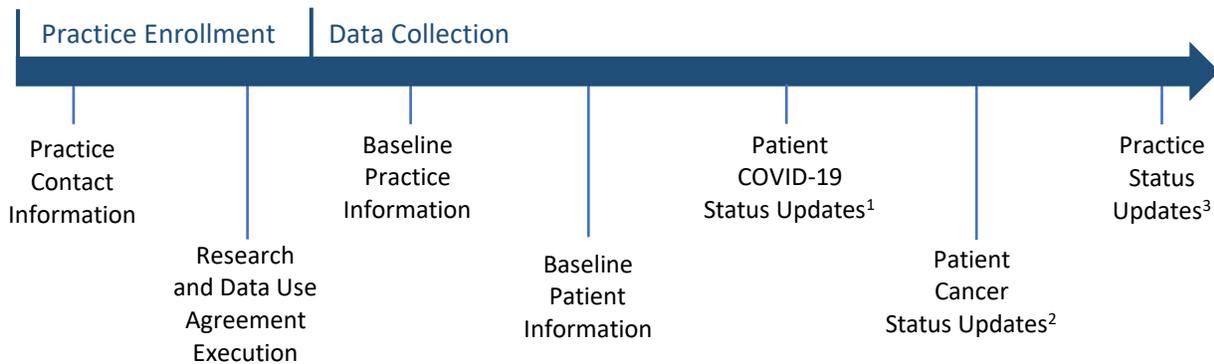
This schedule is intended to ensure consistent reporting across practices. It is important for practices to follow the schedule as close as possible because deviations may impact the quality of data in the registry and accuracy of inferences. However, ASCO acknowledges that adjustments may need to be made for some practices.

Phase	Frequency		
	Baseline	Weekly	Monthly
Baseline Entry			
Baseline Clinical and Demographic Information	●		
COVID-19 Diagnosis, Symptoms, and Treatment	●		
Cancer Diagnosis, Status, and Treatment	●		
Status Updates			
COVID-19 Status Updates		● ¹	
Cancer Status Updates			● ²

¹Weekly until death or complete resolution of COVID-19 symptoms

²Monthly, at a minimum, for at least 12 months, closure of registry, or death (whichever occurs first)

Registry Schedule for Participating Practices



¹Patient COVID-19 status updates should be entered weekly until death or complete resolution of COVID-19 symptoms

²Patient cancer status updates should be entered at least monthly, for at least 12 months, closure of registry, or death (whichever occurs first)

³Practice status updates should be provided at least monthly, as applicable, for at least 12 months