

ASCO[®] Registry

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

Frequently Asked Questions – Updated May 12, 2020

1. Why is ASCO launching the ASCO Survey on COVID-19 in Oncology (ASCO) Registry?

ASCO has extensive relationships with the entire cancer care community, particularly private practices that may be caring for many patients with cancer who have a COVID-19 infection. The ASCO Registry involves submission of a limited data set of patient identifiers to enable participating researchers to update information on their patients' COVID-19 and cancer treatment and outcomes. This longitudinal data will help us understand both the COVID-19 infection outcomes and cancer outcomes, particularly delays or alterations to treatment plans. The American Society of Hematology ([ASH Research Collaborative COVID-19 Registry for Hematologic Malignancy](#)) has similar aims with a focus on hematologic malignancies. The [COVID-19 & Cancer Consortium](#) focuses more directly on COVID-19 treatment and outcomes in patients with cancer, requesting participating institutions to provide follow-up information on 30-day and 90-day outcomes. The ASCO Registry is designed to capture COVID-19 treatments and outcomes as well as cancer treatment and outcomes, including long-term effects for those who recover from COVID-19.

Data collection is of utmost importance during this rapidly evolving global pandemic. Gathering and analyzing data and developing a new evidence-base are essential. We encourage practices to participate in one or more registries and make local decisions about how to enter patient data. Duplicate entry of patient cases is certainly possible and will neither compromise our efforts nor prevent all organizations from working together to understand the overall impact of COVID-19 on patients with cancer.

2. What types of practices/institutions can participate in the ASCO Registry?

The ASCO Registry is open to all U.S. practices/institutions that execute a data use agreement (DUA) with ASCO. All participating practices will be listed on the ASCO Registry webpage. Practices may withdraw from the registry at any time.

3. What are the expectations for ASCO Registry participating practices/institutions?

After executing the DUA, practices will complete an initial survey about the effects the COVID-19 pandemic on their practice. After completing the initial survey, practices will enter baseline and follow-up data on patients with cancer who have COVID-19 disease confirmed. Follow-up data includes information on COVID-19 and cancer treatment and outcomes. Ideally, data entry will be done on a routine basis (weekly or monthly) and practices will attempt to include information from inpatient hospitalizations. Practices may be asked to answer the survey regarding changes to their practice several times over the course of the pandemic.

4. Has the ASCO Registry been reviewed by an Institutional Review Board (IRB)?

Western IRB reviewed the ASCO Registry and determined that it is "exempt from IRB review because it does not meet the definition of human subject as defined in 45 CFR 46.102." ASCO encourages practices/institutions to rely on the Western IRB approval letter located [here](#).

5. Is the ASCO Registry an acceptable registry for a Merit-based Incentive Payment System (MIPS) improvement activity?

ASCO's Survey on COVID-19 in Oncology Registry (ASCO Registry) is an acceptable clinical trial registry for the attestation of the high-weighted practice Improvement Activity (IA), "COVID-19 Clinical Trials related to the Emergency Response & Preparedness," under the Merit-based Incentive Payment System (MIPS).

CMS' validation criteria for this IA states that the MIPS eligible clinician or group must provide evidence of submission of clinical data to the clinical data repository or registry supporting the COVID-19 clinical trial (i.e. screenshot from the participating clinical data repository or clinical data registry). As with all IAs, documentation requirements should remain available for at least 6 years and are expected as supporting the performance of the IA in the event the eligible clinician/group was asked by CMS to provide further information/validation of their performance.

6. What information will ASCO be reporting from the ASCO Registry?

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 aggregated, de-identified information about the demographics of patients with cancer with a COVID-19 infection, the treatments they receive for the infection, their outcomes from the infection as well as any modifications to their cancer treatment plans and, eventually, their cancer treatment outcomes. ASCO will strive to provide reports at least monthly. However, timing will depend on the number of cases reported to the registry, and entry of the outcome information.

7. Will data from the ASCO Registry be available for researchers for further analysis?

Yes. Consistent with the Society's [Information Sharing Policy](#), ASCO will make deidentified Registry data available to researchers (both those at Registry sites and those not involved with the Registry) for further analysis. The timing of data release will depend on the number of cases reported to the registry, and entry of the outcome information. ASCO will review requests for Registry data from individuals and entities that submit a research proposal that complies with ASCO's requirements for data access. ASCO will promote access to information for projects that address the needs of patients with cancer, including marginalized populations and communities. ASCO will promote authenticity, quality, reliability and integrity of information and analyses. ASCO will promote fair access and efficiency in the use and sharing of ASCO Information within the bounds of this Policy. ASCO will provide updates at the [ASCO Registry website](#) when reports from the Registry are available.

8. When will identifiable data be destroyed?

Once the ASCO Registry is closed to new data submission, ASCO will deidentify the data and destroy identifiers.

9. Will the data submitted to the registry be stored offshore or accessed by users outside the US?

No, the data is stored onshore in the US and will only be accessed by a small, domestic analytic team.