

Update for Week of March 30, 2020 to the Joint Statement on Coronavirus COVID-19
From Lung Cancer Advocacy Groups

As of March 30, 2020, cases of the virus surge in countries around the world. The United States now has the highest number of COVID-19 cases globally. The CDC has issued a travel advisory for the New York tri-state area, which has the highest number of cases in the country.

In this week's update, we discuss lung cancer treatment and clinical trials in the era of COVID-19. **The information presented in this update, though current, is a work-in-progress built on very little data. Implementation across institutions and trial sites will vary based on availability of resources and healthcare workers.**

Also, please don't forget to check out the Resources list.

Lung cancer treatment and COVID-19

The oncology community is currently balancing treatment decisions for lung cancer patients, in light of the COVID-19 pandemic. Two factors are being used to decide what's best for our patients:

- Whether a delay in cancer diagnostic tests or treatment presents more risk than potential COVID-19 exposure in the clinic
- Whether a difference in treatment approach can help reduce clinic visits and interactions with others

The CDC continues to recommend [social distancing](#) to help decrease transmission of COVID-19 within the community. Social distancing measures, such as cancelling public gatherings and avoiding crowds, can slow the spread of the virus and spread cases out over a longer period of time, which can help hospitals provide care while avoiding being overwhelmed by patients. Social distancing helps "flatten the curve" in the spread of an infectious disease. This is especially critical because hospitals and health systems are working at full capacity. Flattening the curve ensures that systems are functional and people who require care the most can get the attention they need. The CDC recommends a distance of [6 feet or 2 meters](#) as the minimum distance between individuals as part of COVID-19 mitigation strategy.

Currently, lung cancer patients may need to engage with the oncology care system for the following reasons:

- clinic visits
- tissue and liquid biopsies
- surgical procedures
- infusion sessions for chemotherapy or immunotherapy (or both)
- refill targeted therapy drugs
- radiation treatments
- hospital admissions

- blood draws for laboratory tests, and
- imaging tests to check if treatments are working

Also, family members may sometimes accompany patients when they are visiting their doctors.

[Recent studies](#) out of China suggest that hospital admissions and repeated clinic visits increase the risk of COVID-19 exposure for patients. Further, [a JAMA Oncology study](#) reported that the infection risk for cancer patients in a tertiary care institution was 2-fold higher than the cumulative incidence observed in the city of Wuhan over the same time period. In light of these data and the rapidly evolving COVID-19 pandemic, the oncology community has come up with the following suggestions for cancer treatment. Please be advised that these recommendations are subject to change.

Small Cell Lung Cancer (SCLC):

If you have a confirmed diagnosis, you may not wish to delay treatment (such as chemotherapy and radiation). You and your doctor should discuss what's right for you.

Early stage non-small cell lung cancer (NSCLC) (Stage I to IIIB):

- If you have already had surgery, your doctor may decide to not start with adjuvant chemotherapy and/or radiation.
- If you have not yet had surgery, you and your doctor may decide to wait on the surgery or your doctor may suggest stereotactic body radiation therapy (SBRT).
- If you are currently having chemo-radiation, your doctor may decide to continue with your treatment or wait on additional treatment.

Advanced stage non-small cell lung cancer (NSCLC) (Stage IIIC-IV):

- If you are on a targeted therapy (pill), you may continue with your treatment as planned. Make sure to check with your doctor and pharmacist to ensure an adequate supply of your cancer medication.
- If you are already on immunotherapy or chemotherapy, your doctor may decide to continue with your treatment, space out infusions, or postpone treatment. They may decide to have you receive infusions at your local clinic or even home infusion, as needed.
- If you are already undergoing radiation therapy, your doctor may choose to hold off on additional treatment, reduce the number of treatments, or keep you on treatment as planned, based on your individual health situation.

Several recent forums have discussed the management of lung cancer during the COVID-19 pandemic. Topics that are currently being addressed by lung cancer providers/thought leaders include:

- How to determine whether pneumonitis is resulting from checkpoint inhibitor or COVID-19 infection

- Should immunotherapy be withheld from patients whose tumors do not have known driver mutations (as determined by molecular testing)?
- Spacing out or postponing infusions for patients on pemetrexed or immunotherapy maintenance
- Reducing the number of fractions used in radiation therapy
- Uncertainty regarding how COVID-19 treatments in clinical trials (such as remdesivir and hydroxychloroquine) may interact with immunotherapy drugs and tyrosine kinase inhibitors
- The growing role for liquid biopsies in places where surgical biopsies are not currently practical (use of mobile phlebotomy too)
- Challenges of spacing out chemotherapy schedules in light of current reimbursement
- Growing role for telemedicine (effective for managing patients but loss of doctor-patient bond)
- Educating others on their care teams to overcome lung cancer nihilism and stigma

All treatment decisions should be made jointly by you and your doctor. Do not change your treatment plan or doctor's visit without consulting your doctor first.

Telehealth or remote consults may be an option for checking in with your doctor. Also, there may be the option to be referred to a "COVID-19-free" hospital or treatment center.

Clinical trials and COVID-19

Clinical trials continue to be a source of life-saving therapies for lung cancer patients. The COVID-19 pandemic has affected the conduct of clinical trials due to the following reasons:

- Questions related to safety of patients traveling to trial sites and undergoing trial-related procedures
- Potential shortage of healthcare providers to conduct trial-related activities
- Interruptions to the supply chain of the drug(s) being tested

The US Food and Drug Administration has recently issued [guidance](#) to help clinical trial sponsors figure out the best approaches to ensure that trials can proceed within resource-constrained settings. A clinical trial sponsor in this case is defined as any entity (for example, a pharmaceutical company) involved in the development and testing of drugs and other interventions in clinical trials. Below we have summarized key points from the FDA guidance that are important from the patient perspective.

For clinical trials that are already ongoing:

- Sponsors should consider each circumstance, assess the potential impact on the safety of trial, and modify study conduct accordingly. Decisions regarding this could include continuing trial recruitment, continuing use of the new drug(s) for patients already involved in the trial, and the need to change patient monitoring schedules throughout

the trial. Clinical trial participants should be kept updated on any changes that a sponsor decides to implement.

- Sponsors, doctors involved in the trials, and Institutional Review Boards (IRBs) may decide that the protection of a patient's safety, welfare, and rights would be best served by continuing or by discontinuing use of the investigational product or participation in the trial. However, such decisions will depend on the specific circumstances of the clinical trial and the patients enrolled.
- Given that trial participants may be unable to come to investigational sites due to protocol-specified visits, sponsors should assess whether alternative methods for safety evaluations could be implemented when necessary and feasible. Additionally, in deciding to continue or discontinue use or administration of the new drug(s), sponsors should consider whether the safety of participants can be ensured by implementing the alternative approach of monitoring such as local scans and blood tests. Sometimes, patients may require additional safety monitoring.

Several sponsors already have different measures in place to allow conduct of clinical trials and avoid as much disruption as possible, such as:

- Allowing patients to have blood draws and CT scans at local cancer centers and clinics
- Shipping drug supplies to patients, especially for targeted therapy (pills) trials
- Remote consent
- Mobile phlebotomy

If you are part of a clinical trial, we recommend you discuss your trial participation immediately with your research team. If you were considering enrolling in a clinical trial, you may want to discuss with your treating physician what options are available for you. **Any decision about trial participation should be made jointly by you and your healthcare team.**

Resources and websites:

1. IASLC's Guide to COVID-19 and Lung Cancer – <https://www.lungcancernews.org/iaslcs-guide-to-covid-19-and-lung-cancer/>
2. The National Cancer Institute has a special website for COVID-19 and emergency preparedness. Coronavirus: What People with Cancer Should Know - <https://www.cancer.gov/contact/emergency-preparedness/coronavirus>
3. We are following updates provided by the World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC), which can be found here:
 - <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>
 - <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
4. Johns Hopkins [Coronavirus Resource Center](https://coronavirus.jhu.edu/) is one of the best places to get current updates. <https://coronavirus.jhu.edu/>

5. **Interactive map of US COVID-19 cases by state** - <https://www.politico.com/interactives/2020/coronavirus-testing-by-state-chart-of-new-cases/>
6. **The One-Two Punch: Cancer And Coronavirus (an important perspective for cancer patients)** - <https://www.forbes.com/sites/miriamknoll/2020/03/20/the-one-two-punch-cancer-and-coronavirus/#73744a4358e6>
7. You can find information specific to your state or city or town on your health department's website.
 - A list of **state department of health** websites can be found here: <https://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html>
 - A list of **local health department** websites can be found here: <https://www.naccho.org/membership/lhd-directory>
8. The **American Medical Association** is also maintaining a resource website for healthcare providers. You can find more information here: <https://www.ama-assn.org/delivering-care/public-health/covid-19-2019-novel-coronavirus-resource-center-physicians>
9. If you cannot avoid air travel, check out this handy article on "**Dirtiest Places on Airplanes: How to Avoid Germs**" <https://time.com/4877041/dirtiest-places-on-airplanes/>



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