



Advanced therapies in the COVID-19 pandemic

Guidelines for moving forward

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The COVID-19 pandemic presents all of us with a dynamic, disruptive challenge unlike anything most of us have experienced in our lifetime. Here are suggestions to help advanced therapy developers navigate this challenging time.

The FDA's [new guidance](#) on the conduct of clinical trials during this pandemic is a good place to start. This concise guidance acknowledges that there is no one-size-fits-all solution at this unprecedented time. "FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures."

In addition, here are five further experience-based guidelines that Vineti is keeping in mind as we work with our biopharmaceutical clients and ecosystem partners.

Protect patient safety, remember patient need

Cancer, genetic disorders, and other conditions addressed by advanced therapies don't stop in the era of COVID-19. There are patients out there who need their product. Now, we need new ways to get those drug products to them safely.



Advanced therapies that require cell collection and/or delivery at academic medical centers face the greatest challenge. All hospitals, especially large academic centers in urban areas, are understandably under greater strain, face new capacity demands, and are requiring tougher safety protocols. Patient safety is also paramount – vulnerable patients with pre-existing conditions shouldn't be near COVID-19 wards. Some patients may have new questions about participating in a trial at this point.

Here, something we call the "80/20" rule can be helpful. It's common to have about 80 percent of your patients affiliated with 20 percent of the clinical sites you work with. Start by understanding how those "20 percent" sites are proceeding with clinical trials or commercial cell and gene therapies at this moment in time. Do they need additional support? Do other clinical sites have the bandwidth to do more right now? Even if operating at a lower volume, a clinical trial or commercial product can still make a life-saving difference for cancer patients.

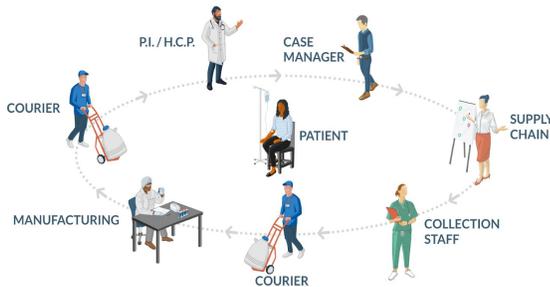
Protect your people

The safety of the advanced therapy community is also vital. And because cell and gene therapies involve so many different stakeholders across distributed ecosystems, health and safety concerns are complex. Some teams, such as commercial or IT groups, can more easily work remotely. Others, such as R&D, clinical operations, logistics, supply chain, or manufacturing, may require working out of specialized shared facilities with other people.

Fortunately, some such roles requiring co-location already operate with strong sterility and other "clean room" practices in place, and can be further adapted to social distancing. Others, especially roles in logistics and supply chain, require collaborating with courier partners to promote shared safety.

The recent FDA guidance and amended clinical protocols allow for further safety enhancements, such as shifting some trial components to out-patient or in-home settings where appropriate.

Step up supply chain vigilance and communication



Advanced therapy supply chains always carry risks – and now those are larger than ever before. Widespread disruptions to commercial flight schedules can affect cell collection, drug product delivery, and the overall patient treatment timeline. Patients may have a more difficult time getting to procedures. Hospital logistics teams may have new and competing priorities.

Here, constant monitoring and communication is key. If major airlines are not currently able to meet your drug product timelines, cargo carriers may be available. Communicate with your collection and infusion centers daily – they are also juggling a constantly changing situation.

Monitor manufacturing, wherever it happens

Whether you operate your own manufacturing or use a contract manufacturer, one thing is certain – it’s “business as usual” for no one right now.

If you operate your own manufacturing facility, a key focus is taking care of your employees, which will in turn help make sure your products are safe. Increased social distancing, increased sterility, and vigilant health monitoring are all key. Some facilities may be going towards more staggered shifts, for example, to allow for greater social distancing among team members.

If you work with a contract manufacturer, increased communication is key. Do you still have the manufacturing slots you planned on, and do you have visibility into manufacturing timelines? How are your manufacturing partners protecting their facilities and team? As the sponsor, product safety and quality is ultimately your responsibility.

Strengthen your systems and security

A remote workforce brings new IT security risks. Team members working from home and working on their own wifi networks can introduce new security weaknesses. Make sure your SOC (Security Operation Center) has stepped up its monitoring. Have remediation strategies in place.



Remote work also raises new system capacity demands. If you have applications that are behind your network, can your VPN handle the increased load as more team members require remote access? Are

all Tier 1 applications up and running in this shifting scenario? Given the shift in work patterns, performance issues should be anticipated and addressed proactively.

We know that some trials have [paused for now](#), and we'll be here to help when they resume. If you have questions about advanced therapy work in the era of COVID-19, please [let us know](#). We're continuing our operations to support our advanced therapy partners and the patients they serve.

About the authors



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