

# Regenerative Medicine and Cell Therapies: Federal Funding is Needed for COVID-19 Clinical Trials

 Alliance for  
Cell Therapy Now  
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## Therapies are Needed for Severely Ill Patients with COVID-19

More than 19 million Americans have tested positive for COVID-19 and more than 335,000 Americans have died. In its most severe form, COVID-19 leads to acute respiratory distress syndrome (ARDS)—a life-threatening lung injury that allows fluid to leak into the lungs and makes it difficult for patients to breathe. The number of hospitalizations in the U.S. has reached an all-time high, exceeding 100,000 since the beginning of December. According to multiple recent studies [cited by the Centers for Disease Control and Prevention](#) (CDC):

- 14% of patients in the U.S. were hospitalized, and among all hospitalized patients, 26 to 32% were admitted to the intensive care unit (ICU).
- Anywhere from 20 to 42% of hospitalized patients and 67 to 85% of patients admitted to the ICU develop ARDS.
- 39 to 72% of patients admitted to the ICU for COVID-19, die.
- Elderly patients and minorities are at greatest risk of serious complications and death.

While significant progress has been made on vaccines, and therapies are beginning to emerge, to date no therapy has shown significant benefit for severe cases. There is an urgent need for new modalities—that are broad-acting and safe—to help severely ill patients with COVID-19.

## Regenerative Medicine and Cell Therapies Show Promising Results

Early evidence shows that regenerative medicine and cell therapies (RMCTs)—and in particular, mesenchymal stromal cells (MSCs)—can play a key role in helping severely ill patients with COVID-19, given their immunomodulatory and anti-inflammatory characteristics.

- A recent [systematic review and meta-analysis](#) led by researchers at the Mayo Clinic, Duke, Emory, Case-Western, and University of Miami, showed a positive trend toward improved pulmonary function, reduced lung inflammation, and reduced mortality for patients with ARDS.
- More than 100 published review articles highlight the potential of MSCs in treating patients with COVID-19.
- At least 100 clinical studies are now underway that explore the potential of RMCTs for patients with COVID-19, 79 of which are focused specifically on the use of MSCs.
- Of the 79 MSC clinical trials, 27 (one-third) are being conducted in the United States.
- Early published results from 21 MSC clinical studies for COVID-19 show safety and efficacy.

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To date, no approved therapy has shown significant benefit for severely ill COVID patients

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At least 100 clinical trials are exploring the use of regenerative medicine and cell therapies for patients with COVID-19

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Despite their promise, less than one-half of one percent of federal funding for clinical trials has been used to support research on regenerative medicine and cell therapies

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Congress and the Administration should direct federal funding toward clinical trials exploring use of regenerative medicine and cell therapies for COVID-19 and other serious conditions

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## Federal Investment is Lacking

Early clinical studies are promising, but large-scale, randomized, placebo-controlled clinical trials that take into account the evolving standard of care and current mortality rates are needed to confirm early results and help bring safe and effective treatments to patients in need. The key barrier to conducting such trials is lack of federal funding.

- Of the 27 clinical studies exploring use of MSCs for COVID-19 patients in the U.S., only one Phase 1 trial—directed towards cancer patients—is being funded by the National Institutes of Health (NIH) through the National Cancer Institute.
- Of the more than \$10 billion in supplemental funding Congress appropriated for vaccines and therapies, little or no funds have been directed towards promising regenerative medicine and cell therapies for patients with COVID-19.
- Less than one-half of one percent of total NIH funding has been used to support clinical trials for regenerative medicine and cell therapies.
- While the 21st Century Cures Act provided \$30 million in funding for regenerative medicine research, such funding expired on September 30, 2020. None of the funding awarded under this program was directed toward clinical trials using MSCs.

## Congress and the Administration Should Act

As COVID-19 and related hospitalizations continue to surge across the U.S., there are no approved therapies for seriously ill patients.

While vaccines are now becoming available, it will take months for Americans to get vaccinated, and many may choose to forgo vaccination. Millions of Americans will continue to contract COVID and thousands more will die.

RMCTs—and in particular, MSCs—show promise for treating seriously ill patients with COVID-19, but large-scale, randomized, placebo-controlled trials—which are needed to confirm efficacy—cannot move forward without federal partnership and support.

Both Congress and the Administration should direct federal funding toward clinical trials exploring the use of RMCTs—including MSCs—for COVID-19 and other serious, life-threatening conditions.

### About Alliance for Cell Therapy Now

Alliance for Cell Therapy Now (ACT Now) is an independent, non-profit organization guided by leaders representing academic and medical institutions, industry innovators, and patients, that is working to advance safe and effective regenerative medicine and cell therapies for patients in need. For more information, go to [www.allianceforcelltherapynow.org](http://www.allianceforcelltherapynow.org).

### For More Information

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