

The Need for Federal Investment in Cell-Based Therapies for Patients with COVID-19

September 2021



Alliance for
Cell Therapy Now

Advancing Regenerative Medicine and Cell Therapies for Patients in Need

Executive Summary

As the nation continues to face the unprecedented and growing challenges of the coronavirus pandemic, the number of Americans that are contracting COVID-19, becoming hospitalized, and in many cases—dying—is high and continuing to grow. More than 40 million Americans have tested positive for COVID-19 and more than 650,000 Americans have died. The combination of the now predominant Delta variant—which is far more contagious and causes more severe illness—and the fact that more than 45% of the American population still remains unvaccinated, is driving surges in hospitalization across the country, with many hospitals now canceling elective surgeries to make room for COVID-19 patients.

There is an urgent need for new treatments to help reduce the severity of illness, the number of hospitalizations, and death related to COVID-19. Evidence from numerous clinical studies shows that cell-based therapies can play a key role in helping severely ill patients with COVID-19, given their immunomodulatory and anti-inflammatory characteristics.

At least 130 clinical studies have been launched that explore the use of cell-based therapies for patients with COVID-19, 52 (or 40%) of which are being conducted in the United States. At least 175 peer-reviewed articles have been published that describe the promise or potential of these therapies for treating COVID-19 patients. One recent meta-analysis and systematic review led by researchers at the Mayo Clinic in collaboration with several other academic leaders showed that MSC cell administration to hospitalized patients with COVID-19 was associated with a 69% reduction in all-cause mortality risk and a 64% reduction in severe adverse events.¹

While results from clinical studies are promising, the vast majority of such studies (89%) are either Phase 1 or Phase 2 studies. Large-scale, randomized, placebo-controlled clinical trials are needed to confirm early results and help bring safe and effective treatments to patients in need.

The largest barrier to conducting clinical research related to cell-based therapies is the high cost of conducting these studies. The financial barriers associated with clinical trials are particularly problematic for academic and research institutions and small biotechnology companies, who are responsible for nearly all of the clinical trials being conducted for COVID-19 both in the U.S. and abroad. Federal funding is needed to help bring promising cell-based therapies to patients with COVID-19 and other serious and life-threatening conditions.

The Administration recognizes the lack of reliable and accessible treatments for COVID-19 and the need for investment in the development and manufacturing of therapies. Both the January 21, 2021 [Executive Order](#) and the [American Rescue Plan](#) (which formed the basis for the COVID-19 relief package passed by Congress and signed into law in March 2021) contained policies to accelerate the development of novel therapies to treat COVID-19. In early September 2021, the Administration released a [COVID-19 action plan](#) that also contained actions that support the development and administration of treatments to reduce hospitalizations and save lives.

Congress authorized nearly \$40 billion in funding for vaccines, therapeutics, and other medical supplies within three COVID-19 relief packages—two of which were passed and signed into law in 2020 and one of which was signed into law in early 2021, but none of such funding was directed towards the development of cell-based therapies for patients with COVID-19.

Several Democratic and Republican members of the House of Representatives and the Senate have called for greater investment in the development and manufacturing of cell-based therapies to support patients in need. As Congress considers appropriations for the coming year, as well as a reconciliation package this Fall, it should designate funds for research on cell-based therapies to augment limited options currently available, to help seriously ill patients with COVID-19, as well as patients with other serious and life-threatening conditions.

Evidence from numerous studies shows that cell-based therapies can help severely ill patients with COVID-19, but federal funding is needed to bring such therapies to patients

Therapies are Needed for Severely Ill Patients with COVID-19

More than 40 million Americans have tested positive for COVID-19 and more than 650,000 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.

According to the Centers for Disease Control and Prevention (CDC), the number of cases, hospitalizations, and deaths have increased considerably since July 2021, fueled by the spread of the highly contagious Delta variant, combined with low vaccination coverage in many communities across the country.^{2,3} As of September 11, 2021, [54%](#) of Americans are fully vaccinated.⁴

As the number of COVID-19-related cases, hospitalizations and deaths continues to grow, there is an urgent need for new treatments

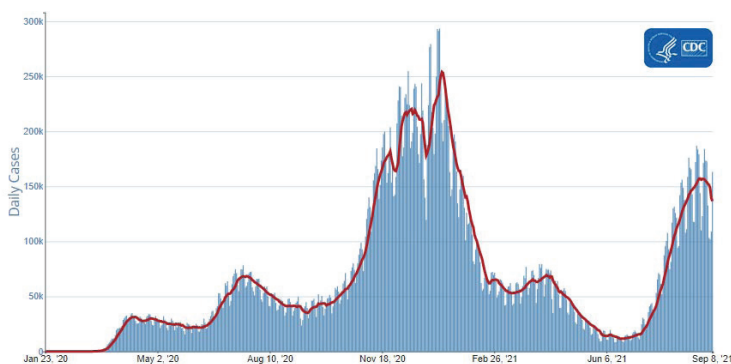


Figure 1. Daily Trends in COVID-19 Cases in the U.S. Reported to CDC (Source: CDC)

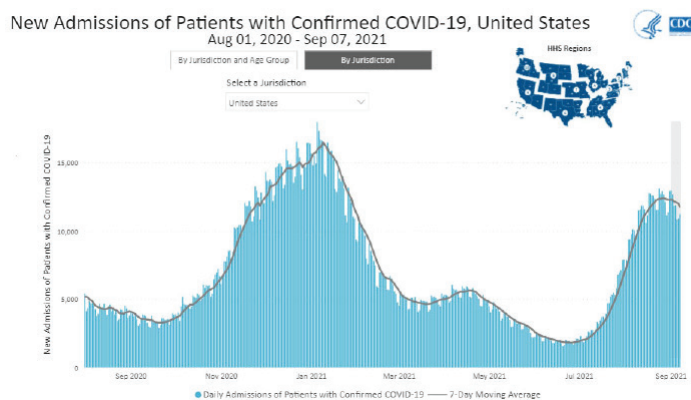


Figure 2. Daily Trends in New COVID-19 Hospital Admissions in the U.S. (Source: CDC)

According to the CDC, the number of Americans hospitalized for COVID-19 has been significantly increasing since July 2021. During the first week of September, the 7-day daily average hospitalization rate was 11,754. Increasingly, children and young adults are being hospitalized, reaching record levels over the last month.⁵

Multiple studies show the dire consequences of COVID-19. Among those hospitalized, 26 to 32% are being admitted to the intensive care unit (ICU), and 5 to 17% are dying.^{6, 7, 8} Mortality rates among those admitted to the ICU are ranging from 26 to 78%.^{8,9} Elderly patients and those with underlying conditions are at greatest risk of serious illness and death.¹¹ There are also significant racial and ethnic disparities. Hispanic, Black, American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander populations are experiencing higher rates of infection and death compared with the White population.¹²

There is an urgent need for new treatments to help reduce the severity of illness and related hospitalizations, prevent progression of hospitalized patients to ICU-level care, and reduce mortality among Americans.

Cell-Based Therapies Show Promising Results for COVID-19

Early evidence shows that cell-based therapies—in particular, MSCs (also referred to as mesenchymal stromal cells, mesenchymal signaling cells, and mesenchymal stem cells)—can play a key role in improving outcomes for severely ill patients with COVID-19, given their immunomodulatory and anti-inflammatory characteristics.

Several published articles describe the promise of cell-based therapies for patients with COVID-19. As summarized in Figure 3, at least 178 review articles have been published in peer-reviewed publications offering insights on the potential or promise of cell-based therapies for patients with COVID-19. The vast majority (171 or 96%) of such review articles describe the role of MSCs in treating COVID-19 patients. A small number of articles also describe the role of T-cells or T-Reg cells, natural killer (NK) cells, induced pluripotent stem cells (iPSCs), and progenitor cells in addressing COVID-19.

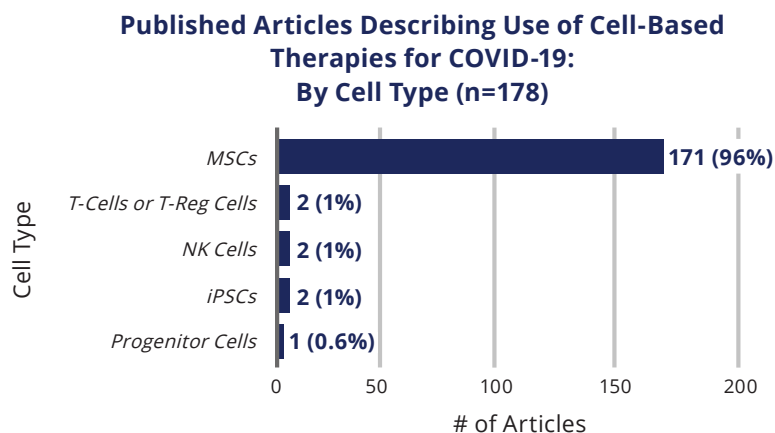


Figure 3. Number of Published Articles Describing the Use of Cell-Based Therapies for COVID-19, by Cell Type

Numerous peer-reviewed publications summarize systematic reviews and meta-analyses of the results of clinical studies that explore the use of MSCs for patients with COVID-19, citing positive results.^{13, 14, 15}

A pre-print publication summarizes a recent systematic review and meta-analysis led by researchers at Mayo, as well as other academic institutions including Case Western Reserve University, Duke University, Emory University, University of Florida, and University of Miami, which indicates that MSC cell administration to hospitalized patients with COVID-19 was associated with a 69% reduction in all-cause mortality risk, a 64% reduction in severe adverse events, and improved pulmonary function, when compared to conventional care.¹⁶

Early evidence shows that MSCs can play a key role in improving outcomes for severely ill patients with COVID-19

Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19

A number of studies have been launched to explore the use of cell-based therapies for patients with COVID-19. As of September 12, 2021, 130 of such studies were listed in www.clinicaltrials.gov.

As summarized in Figure 4, of the 130 studies listed, 40% were or are being conducted in the United States, compared to 60% that were or are being conducted in other parts of the world.

Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19: By Location (n=130)

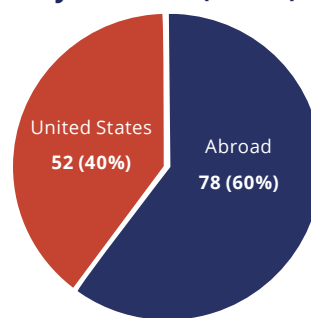


Figure 4. Number of Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Location

As indicated in Figure 5, the vast majority (79%) of clinical studies being conducted are focused on the use of MSCs for patients with COVID-19. Other cell-based therapies are also being explored, including T-cells or T-reg cells (8%), NK cells (5%) and other cells (7%).

Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19 By Cell Type (n=130)

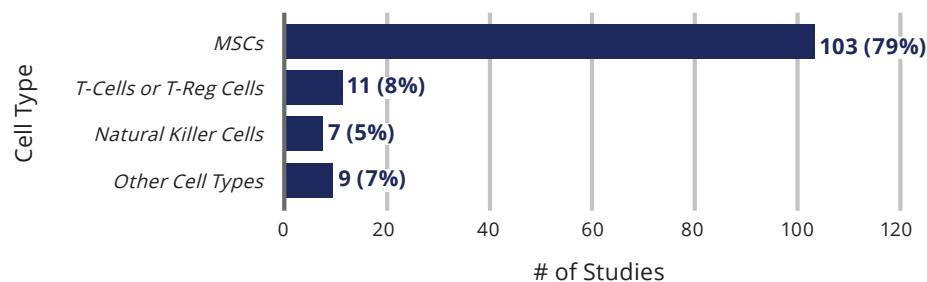


Figure 5. Number of Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Cell Type

There are at least 130 clinical studies exploring the use of cell-based therapies for patients with COVID-19

Majority of Clinical Studies are Early Phase Clinical Trials

As indicated in Figure 6 below, the vast majority (89%) of the clinical studies related to the use of cell-based therapies for COVID-19 that are being conducted worldwide are either Phase 1 (28%), Phase 1/2 (29%), or Phase 2 (32%) studies. Two of the studies are Phase 2/3 clinical trials and only one study is a Phase 3 trial. Six of the studies are based on expanded access use of these therapies.

**All Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19:
By Phase (n=130)**

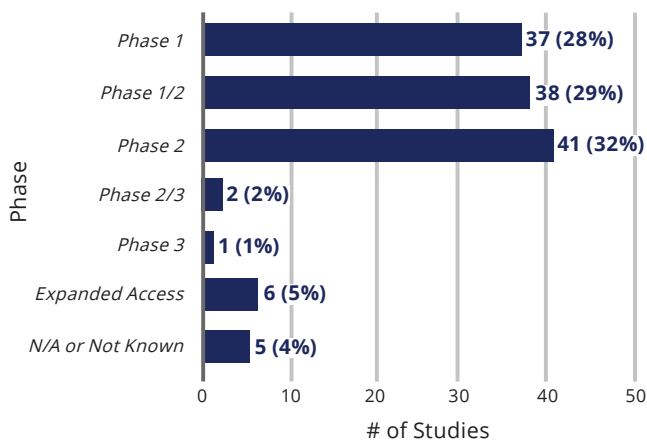


Figure 6. Number of Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Phase

Results are similar for U.S. clinical studies. As summarized in Figure 7, 85% of the clinical studies involving cell-based therapies for COVID-19 patients are either Phase 1 (29%), Phase 1/2 (21%), or Phase 2 (35%) studies. There is one Phase 2/3 clinical trial and one Phase 3 trial being conducted in the U.S. Six clinical studies are based on expanded access use.

**U.S. Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19:
By Phase (n=52)**

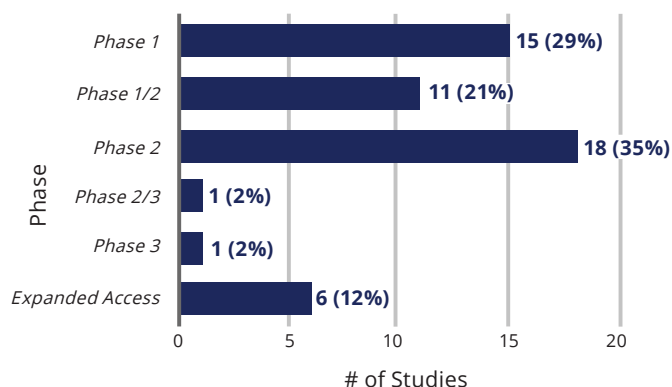


Figure 7. Number of U.S. Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Phase

Results are similar for clinical studies exploring the use of MSCs for patients with COVID-19. The vast majority (87%) of MSC clinical studies being conducted worldwide are either Phase 1 (22%), Phase 1/2 (28%), or Phase 2 (37%) studies. Eighty-two percent of MSC clinical studies conducted in the U.S. are either Phase 1 (19%), Phase 1/2 (21%), or Phase 2 (42%).

The vast majority of clinical studies exploring use of cell-based therapies for COVID-19 are Phase 1 or Phase 2 clinical trials

Academic and Research Institutions Play a Critical Role

Academic and research institutions play a critical role in the development of cell-based therapies for COVID-19, as well as other serious and life-threatening conditions. As summarized in Figure 8, 59% of clinical studies exploring the use of cell-based therapies for patients with COVID-19 worldwide are sponsored by academic and research institutions. Thirty-five percent are sponsored by industry and 5% are sponsored by hospitals.

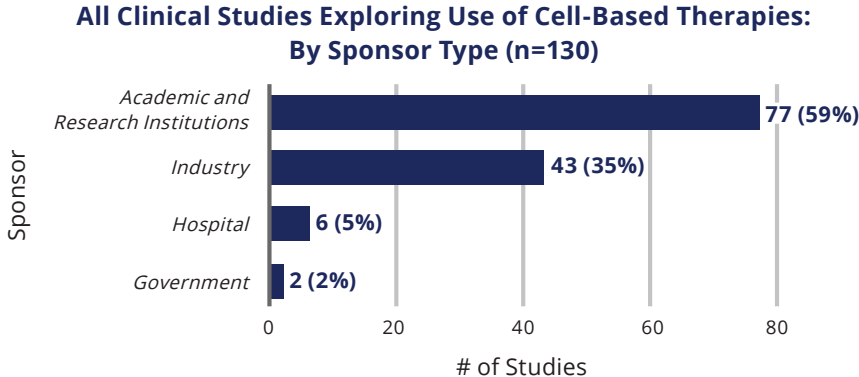


Figure 8. Number of Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Sponsor Type

As summarized in Figure 9, twenty (or 38%) of U.S. clinical studies exploring the use of cell-based therapies for COVID-19 are sponsored by academic and research institutions. Thirty-two studies (or 62%) are sponsored by industry organizations—that are largely small biotechnology companies. Eighteen of the 32 clinical studies in the U.S. sponsored by industry are in collaboration with academic and research institutions or hospitals.

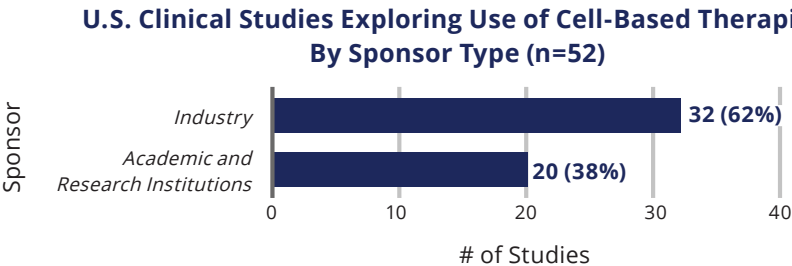


Figure 9. Number of U.S. Clinical Studies Exploring Use of Cell-Based Therapies for COVID-19, by Sponsor Type

Examples of academic and research institutions or hospitals either leading or participating in clinical studies exploring the use of cell-based therapies for patients with COVID-19 in the U.S. include Baptist Health, Baylor College of Medicine, Brigham and Women’s Hospital, Case Western Reserve University, Cedars-Sinai Medical Center, Cincinnati Children’s Hospital, Cleveland Clinic, Dartmouth-Hitchcock, Duke University, Emory University, Fred Hutchinson Cancer Research Center and the University of Washington, Hackensack University Medical Center, Holy Medical Center, Houston Methodist Hospital, Johns Hopkins, Landmark Hospital, Lutheran Hospital, Maimonides Medical Center, Maine Medical Center, Mayo Clinic, MD Anderson Cancer Center, Mount Sinai Icahn School of Medicine, Ochsner Clinic, Providence – Saint John’s Medical Center, Sanford Health, Stanford University, Thomas Jefferson University, University of California (UC) – Davis, UC-Irvine, UC-San Francisco, University of Maryland, University of Miami, University of Michigan, University of Minnesota, University of North Carolina, University of Pennsylvania, University of Pittsburgh, University of Southern California, University of Utah, University of Virginia, WakeMed, and several Veterans Administration (VA) hospitals.

Academic and research institutions are conducting a majority of clinical studies exploring cell-based therapies for COVID-19. Small biotech companies also play a key role

Federal Support is Needed to Bring Promising Treatments to Patients

As noted previously, results from early Phase 1 and Phase 2 clinical studies exploring the use of cell-based therapies—particularly MSCS—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 largest barrier to conducting clinical research related to cell-based therapies is the high cost of conducting studies.¹⁷ The financial barriers associated with clinical trials is particularly problematic for academic and research institutions and small biotechnology companies, who are responsible for nearly all of the clinical studies both in the United States and abroad.

Only one of the 130 clinical studies exploring the use of cell-based therapies for patients with COVID-19 identified in www.clinicaltrials.gov reported receipt of federal funding. In order to advance cell-based therapies to help severely ill patients with COVID-19, federal funding is needed.

The Administration recognizes the lack of reliable and accessible treatments for COVID-19 and the need for investment in the development and manufacturing of therapies. Both the January 21, 2021 [Executive Order](#) and the [American Rescue Plan](#) (which formed the basis for the COVID-19 relief package passed by Congress and signed into law in March 2021) contained policies to accelerate the development of novel therapies to treat COVID-19. In early September 2021, the Administration released a [COVID-19 action plan](#) that also contained actions that support the development and administration of treatments to reduce hospitalizations and save lives.

Congress authorized nearly \$40 billion in funding for vaccines, therapeutics, and other medical supplies within three COVID-19 relief packages—two of which were passed and signed into law in 2020 and one of which was signed into law in early 2021, but none of such funding was directed towards the development of cell-based therapies for patients with COVID-19.

Several Democratic and Republican members of the House of Representatives and the Senate have called for greater investment in the development and manufacturing of cell-based therapies to support patients in need within the FY 2022 appropriations process.

As Congress considers appropriations for the coming year, as well as a reconciliation package this Fall, it should designate funds for research on cell-based therapies to augment limited options currently available to help seriously ill patients with COVID-19, as well as patients with other serious and life-threatening conditions.

Congress should assure that funds are allocated toward the development of cell-based therapies for patients with COVID-19

“To enhance the Nation’s ability to quickly develop the most promising COVID-19 interventions, the Secretary of Health and Human Services (HHS), in consultation with the Director of the National Institutes of Health, shall ... develop a plan for supporting a range of studies, including large-scale randomized trials, for identifying optimal clinical management strategies, and for supporting the most promising treatments for COVID-19 and future high-consequence public health threats...”

The White House. Executive Order on Improving and Expanding Access to Care and Treatments for COVID-19. January 21, 2021.

End Notes

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- ² Centers for Disease Control and Prevention. (2021). *COVID Data Tracker Weekly Review, Interpretive Summary for September 10, 2021*. September 10, 2021. Available at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html#print>.
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Acknowledgements

ACTN would like to thank its Advisory Board members who have provided guidance and input to ACTN's ongoing assessment of the field, including content contained in this report.

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Kyle Richardson
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Acknowledgements

Camillo Ricordi, MD
Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, and Microbiology and Immunology, Director of the Diabetes Research Institute and the Cell Transplant Program, University of Miami

Krishnendu Roy, PhD
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Robin L. Smith, MD, MBA
President and Chair, Stem for Life and Cura Foundation

Piotr P. Witkowski, MD, PhD
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ACTN would like to acknowledge Alice Yu, who was responsible for research, as well as the design and lay-out of this report. ACTN would also like to thank Spoorthi Balu, who assisted with research to support the report. Finally, ACTN would like to thank Janet Marchibroda who conducted research for, and authored this report, with the guidance of the ACTN Advisory Board.

About Alliance for Cell Therapy Now

Alliance for Cell Therapy Now (Alliance) 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 <http://allianceforcelltherapynow.org/>

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