

# Enrollment is open for the ACTIV-1 Phase 3 clinical trial: Immune Modulators.

ACTIV is a public-private partnership advancing research to **prioritize and speed COVID-19 treatments and vaccines.**



ACTIV-1 is a Phase 3 clinical trial evaluating the safety and efficacy of three immune modulator drugs in hospitalized adults with COVID-19.

## Cytokine Storms and Immune Modulators

Some COVID-19 patients experience life-threatening complications because their immune systems release excessive amounts of pro-inflammatory proteins — called a “cytokine storm.”

Immune-modulating drugs temporarily disable parts of the immune system and may minimize the harmful effects of a cytokine storm. The ACTIV-1 trial is studying three immune modulators based on their (1) effectiveness against inflammatory reactions and cytokine storms, (2) safety profile, and (3) availability for large-scale clinical studies.

Visit the ACTIV Therapeutics page: <https://nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>.

Researchers interested in participating in ACTIV-1 can email [ACTIV1@dm.duke.edu](mailto:ACTIV1@dm.duke.edu).

To learn about COVID-19 clinical trial opportunities nationwide, visit the U.S. Department of Health and Human Services’ Combat COVID website at <https://combatcovid.hhs.gov>.

## ACTIV-1 Clinical Trial

- ◆ Adaptive master protocol design enables broad participation and maximum flexibility.
- ◆ Trial will include 2,100 hospitalized adult participants with moderate to severe COVID-19.
- ◆ Participants receive remdesivir and an add-on treatment of either one immune modulator or a placebo. Each drug combination is evaluated for the following:
  - ◇ safety
  - ◇ illness severity
  - ◇ recovery speed
  - ◇ mortality
  - ◇ hospital resource utilization

## Links to More Information

Additional study information is available at [ClinicalTrials.gov](https://clinicaltrials.gov) under study identifier [NCT04593940](https://clinicaltrials.gov/ct2/show/study/NCT04593940) and [activ-1.org](https://activ-1.org).

