Georgia CTSA Rapid Response Team: 48-Hour Approval for COVID-19 Study

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VISION

The Georgia CTSA Rapid Response Team (RRT) was created to establish a standard procedure to dramatically streamline the pre-award approval process for NIH studies, Federally Funded Network Studies, as well as Non-Federal studies needing fast-track approvals.

- High priority, requiring emergency approval for survival
- Public health emergency
- Bioterrorist attack
- Significant or catastrophic event

METHODS

- Each department completes departmental approval.
- If applicable, external/single IRB is notified of urgency.
- Clinical Research Navigator team facilitates the pre-award approval process through all research administrative offices to completion.
- Each office assigns one person to complete the approval and other tasks in real time, working in parallel with other offices.
- Clinical Research Navigator notifies the investigator when study approvals are complete.

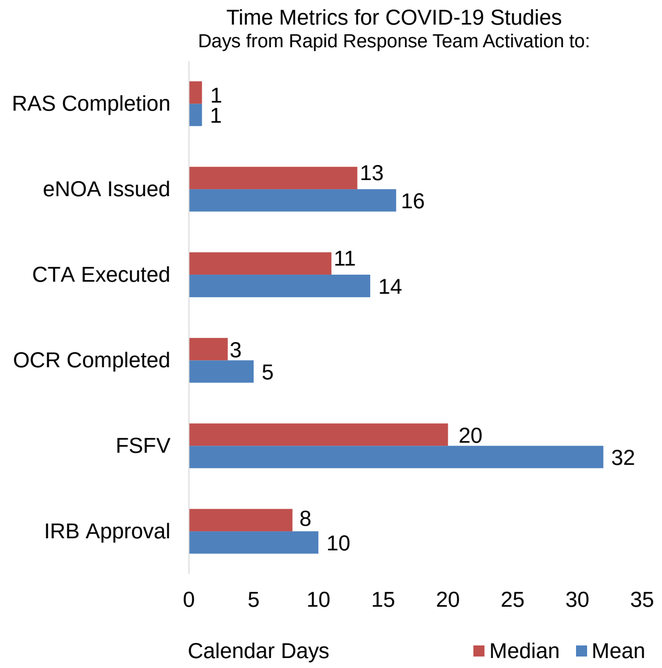
RESULTS

Emory's first COVID-19 patient began receiving infusion therapy of Remdesivir within 48 hours as a result of Georgia CTSA's assistance in coordinating the approvals needed. Georgia CTSA utilized its new Standard Operating Procedure (SOP) for its Rapid Response Team process to obtain fast-track approvals across the Emory system.

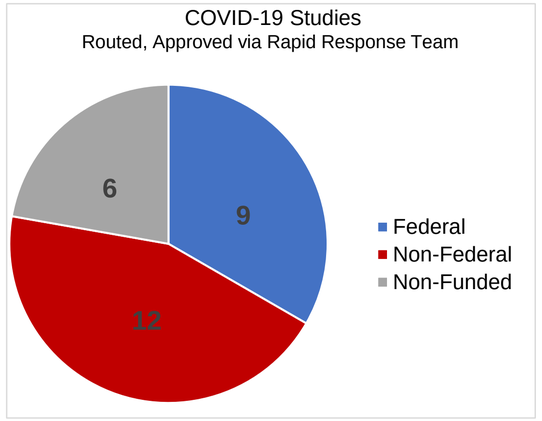
SUCCESSES

The Rapid Response Team expedited and facilitated pre-award approval process for 27 COVID-19 studies through September 2020 and effectively responded to the COVID-19 pandemic at many levels:

- **advancing our understanding of how the immune system fights SARS-CoV-2**
- **providing valuable samples starting with an 80-year-old couple exposed to the disease while on a cruise ship to allow the development of serologic testing**
- **being the highest enrolling site in the world for the Remdesivir placebo-controlled trial. Remdesivir, an anti-viral agent, was recently granted FDA approval**
- **testing the first in human coronavirus vaccine and the first site in the world to enroll older adults in a coronavirus vaccine trial with promising results paving the way for a Phase 3 vaccine trial**



KEY STATISTICS



Total number (N = 27) of COVID-19 high-priority studies that met qualifying criteria for expedited review and approval through Rapid Response Team.

CONCLUSIONS

- The Georgia CTSA Rapid Response Team expedited high-priority studies of experimental therapeutics and vaccines.
- Representatives from Emory research offices worked together in parallel to expedite 27 COVID-19 studies.
- Median time from Protocol Receipt to First Subject First Visit was 20 Days.

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