



SARS-CoV-2 and ARDS Pandemic Experience



Recognized globally for excellence in clinical trial support stemming from our deep roots in statistical science coupled with an unwavering commitment to delivering superior research support. For more than 45 years, Emmes has applied its expertise quickly and effectively to pandemics, including Ebola, Zika, H1N1 and Avian flu studies.

With the COVID-19 pandemic beginning February 2020, the impact to Emmes' business occurred in a number of areas: (1) in the operations of our support of clinical research, pivoting as necessary, to ensure successful implementation of all our clinical research studies; and (2) to be at the forefront of the research activities to use our experience and expertise to conduct fast, collaborative, and quality research studies in COVID-19.

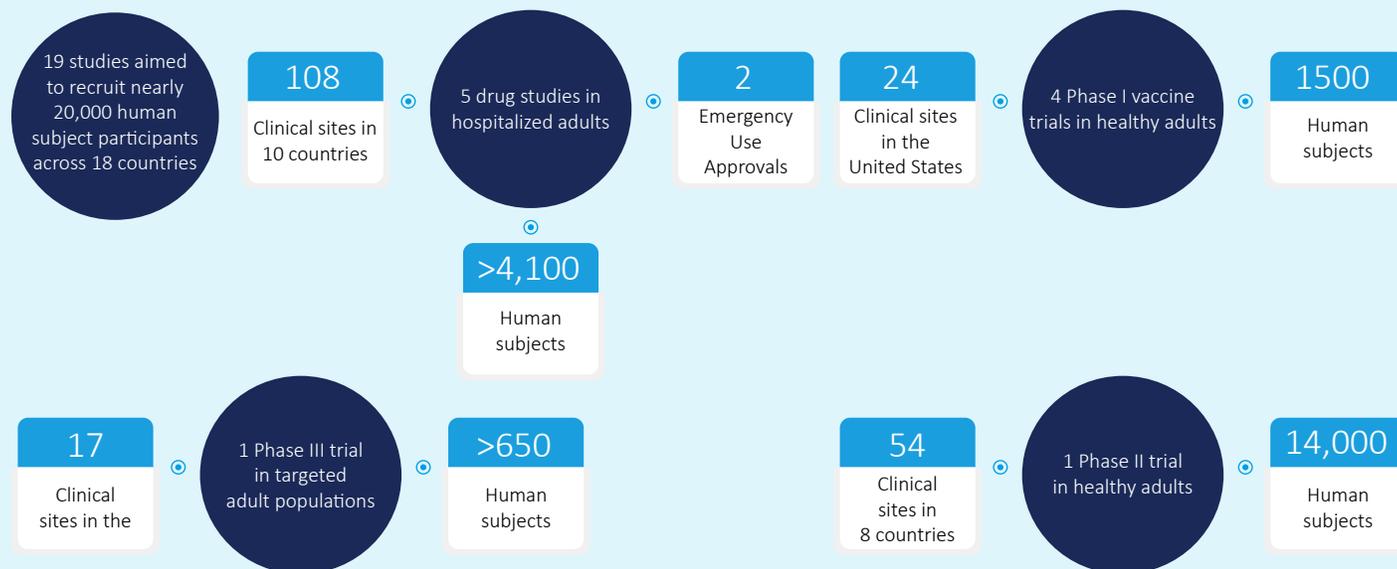
“In the last 500 days, we have designed, implemented, and completed 4 large (1,000 person) treatment trials that have changed the way we treat COVID-19 and changes outcomes for millions of people.

Your team has worked so incredibly hard for all of ACTT and getting to the ACTT-4 database lock is another huge accomplishment.”

Associate Director for Clinical Research



Summary of Emmes' involvement in the COVID-19 effort within the Vaccine and Infectious Disease Therapeutic Research Unit:



Emmes is an industry leader in conducting fast, collaborative, and quality research studies during pandemics.

Illustrative examples include:

- Supporting Phase I–IV influenza clinical trials and natural history studies for bio-pharmaceutical, government and non-profit clients.
- Supporting NIH's response to the 2009 H1N1 pandemic and studies in preparation for other potential pandemic strains.
- Developing standardized protocols, study materials, data collection methods, and uniform quality control processes that have been instrumental in creating a clinical research infrastructure for the rapid and successful conduct of pandemic trials.
- Providing data management, project management, and statistical support of the Phase 1 trial of the Moderna mRNA vaccine. Data from this study supported development of the Phase II and III Moderna trials.

In 2020, Emmes was selected by the National Institute of Health to manage the National Institute of Allergy and Infectious Diseases, Division of Microbiology and Infectious Diseases (NIAID-DMID) sponsored Adaptive COVID-19 Treatment Trials (ACTT) which were pivotal licensure trials of therapeutics for COVID-19 and part of Operation Warp Speed. Statistical, data management, and project management support has continued through 4 phases of ACTT and resulted in the following publications, to date:

- Remdesivir for the Treatment of Covid-19 — Preliminary Report. N Engl J Med 2020 May 22; DOI: 10.1056/NEJMoa2007764.
- Baricitinib plus Remdesivir for Hospitalized Adults with Covid-19. N Engl J Med 2021; 384:795-807 DOI: 10.1056/NEJMoa2031994.

For additional information on our robust pandemic experience, please visit info@emmes.com