# COVID-19 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

**Nearly 25,000 human subjects**

**25+ COVID-19 studies**

**Across 27+ countries**

## 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 high-quality research studies during pandemics, with a focus on developing standardized protocols, materials, and processes for successful clinical trials.**

**Illustrative examples include:**

- Providing full-scope support, including Advantage eClinical, on a three-year Phase III clinical efficacy study evaluating nitric oxide nasal spray as preventative for individuals at risk of exposure to COVID-19 infection.
- Provides data management, statistical, project management and administrative support for the HVTN and CoVPN. HVTN's mission is to develop a safe and effective HIV vaccine, while CoVPN conducts Phase III efficacy trials for COVID-19 vaccines and antibodies.
- Supports a Biopharma companies' Phase I Intranasal COVID-19 vaccine trial in adults and adolescents by providing comprehensive services, including site feasibility, mgmt. & monitoring, biostatistics & pharmacovigilance.

**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. The ACTT trials resulted in two Emergency Use Authorizations (EUA). 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 COVID-19 experience, please visit
**www.emmes.com/vaccines-and-Infectious-diseases**



Emmes