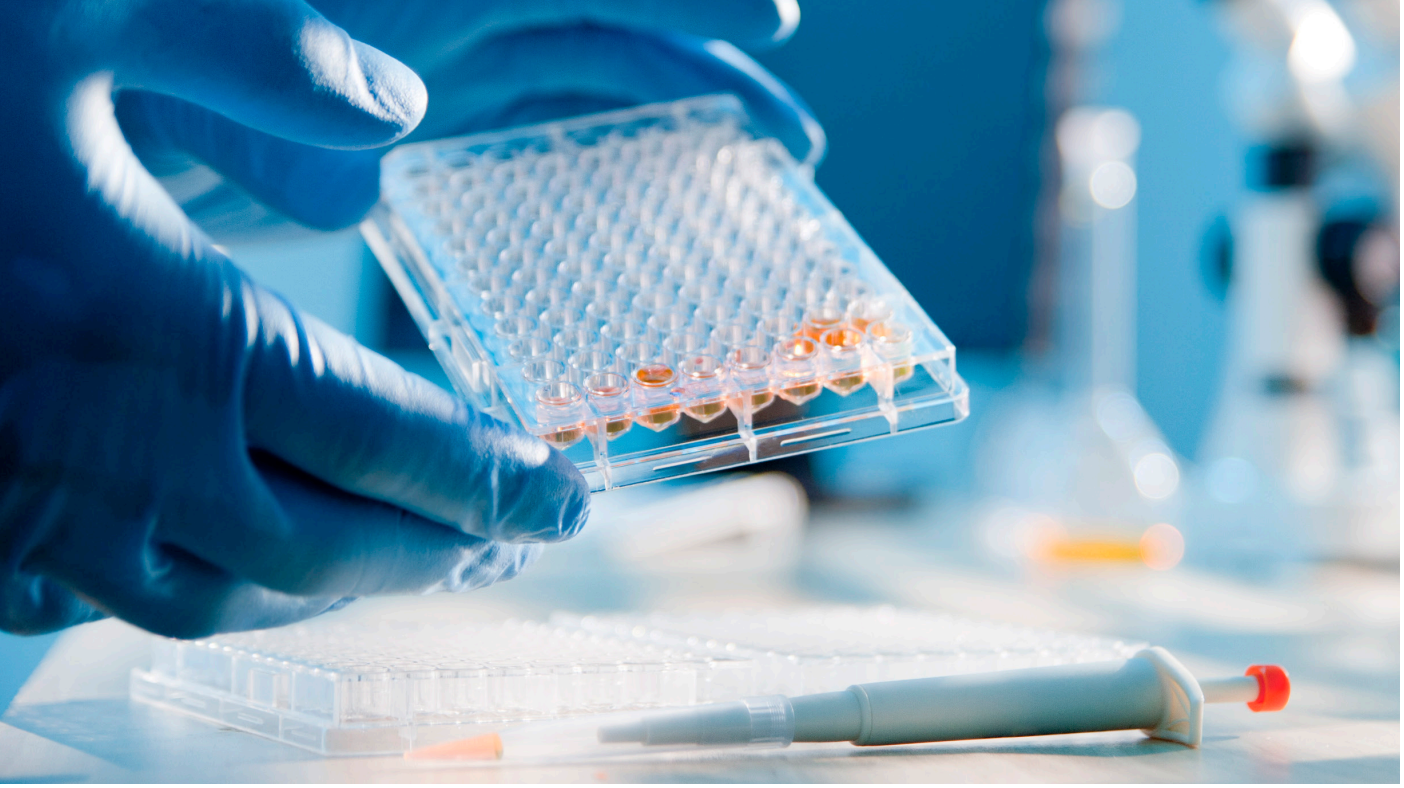
Emmes Public Health Emergency of International concern (PHEIC) Response

Emmes has been at the forefront of pandemic and epidemic response for the past 40 years. From HIV to COVID-19, Emmes has successfully met accelerated timelines and provided a wide spectrum of clinical trial support services for therapeutic and vaccine trials under challenging conditions.

HIV	Zika	Influenza	COVID-19	Ebola
70	10	110	25+	9
Clinical studies	Clinical studies	Clinical studies	Clinical studies	Clinical studies

Fact Sheet



Experience at a glance

Emmes study teams mobilize their substantial experience in supporting pandemic trials to provide data management, project management, statistical support and analyses, and clinical monitoring services.

Emmes has developed standardized protocols, study materials, quality control and data collection processes, including standard eCRFs using our proprietary electronic data collection system, Advantage eClinical, that allow for flexibility, rapid setup of databases, accelerated study start-up, and successful conduct of clinical trials. Our standardized protocols have allowed us to provide full databases in less than 2 weeks for multiple trials.

COVID-19

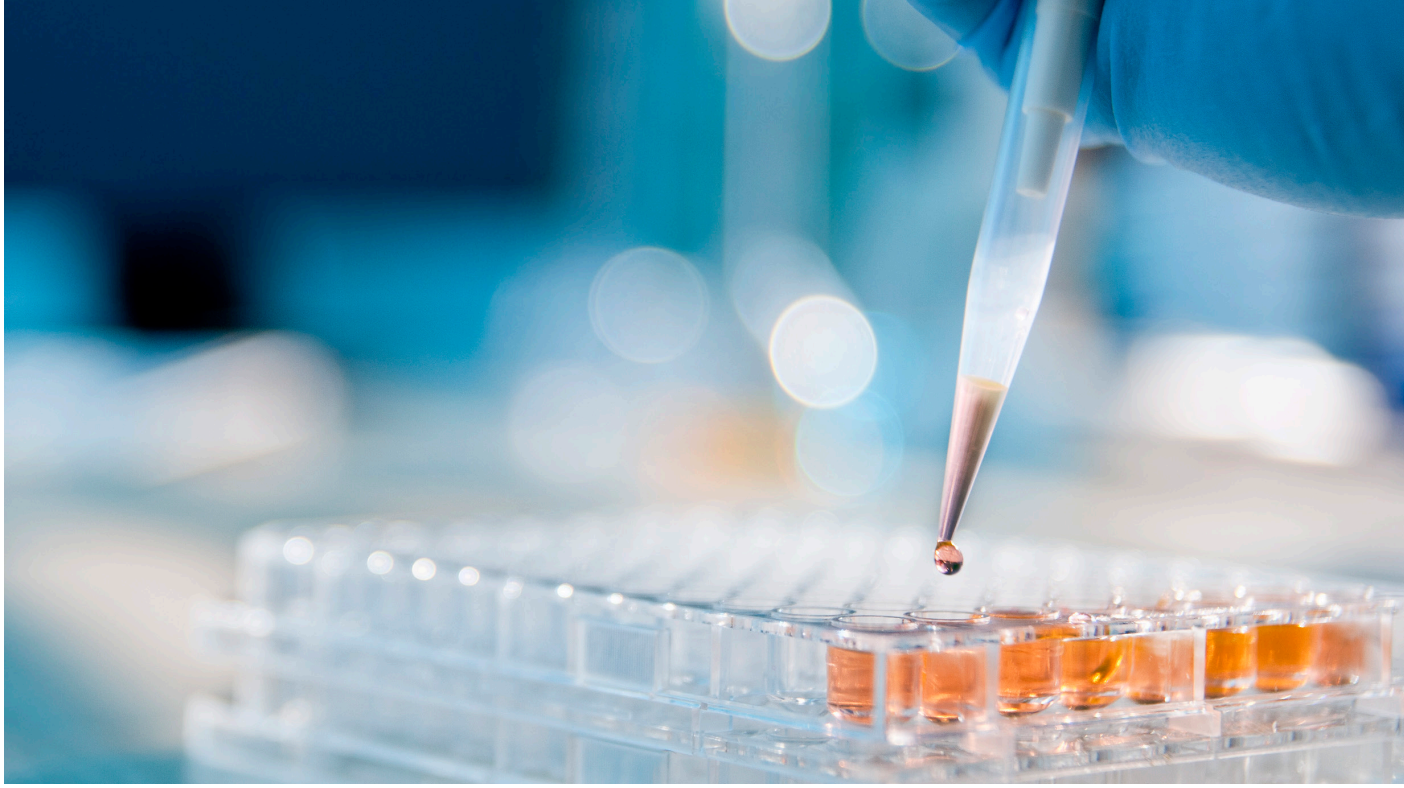
Internet randomization available 2 days after receiving the ACTT COVID-19 therapeutics protocol, with full database available 7 days later.

H5N1

Live electronic data capture collection available 9 days after receiving H5N1 vaccine protocol.

Ebola

Clinical data management system in place 20 days after receipt of near-final protocol for domestic Ebola vaccine trial and 15 days after pre-cost authorization award for international Ebola vaccine study.



Key highlights and accomplishments

Emmes is an industry leader in conducting fast, collaborative, and quality research studies during pandemics. These clinical trials supported by Emmes was a step in the process to licensure of a pandemic vaccine (Moderna's mRNA COVID-19 vaccine), and let to 2 pandemic therapeutics (remdesivir and baricitinib, for the treatment of hospitalized COVID-19 patients), and 5 publications in the New England Journal of Medicine [1-5].

- Emmes provided data management and statistical support for the Adaptive COVID-19 Therapeutic Trial (ACTT) that examined 4 different therapeutic modalities at a total of 93 clinical sites and led to the licensure of 2 therapeutics. Emmes set up internet randomization in 2 days and the full database in 9 days after receipt of the clinical trial protocol.

- Emmes supported 4 coordinated Zika vaccine studies through DMID and the Henry Jackson Foundation, as well as a natural history study. These studies were all implemented on expedited timelines in an epidemic environment.

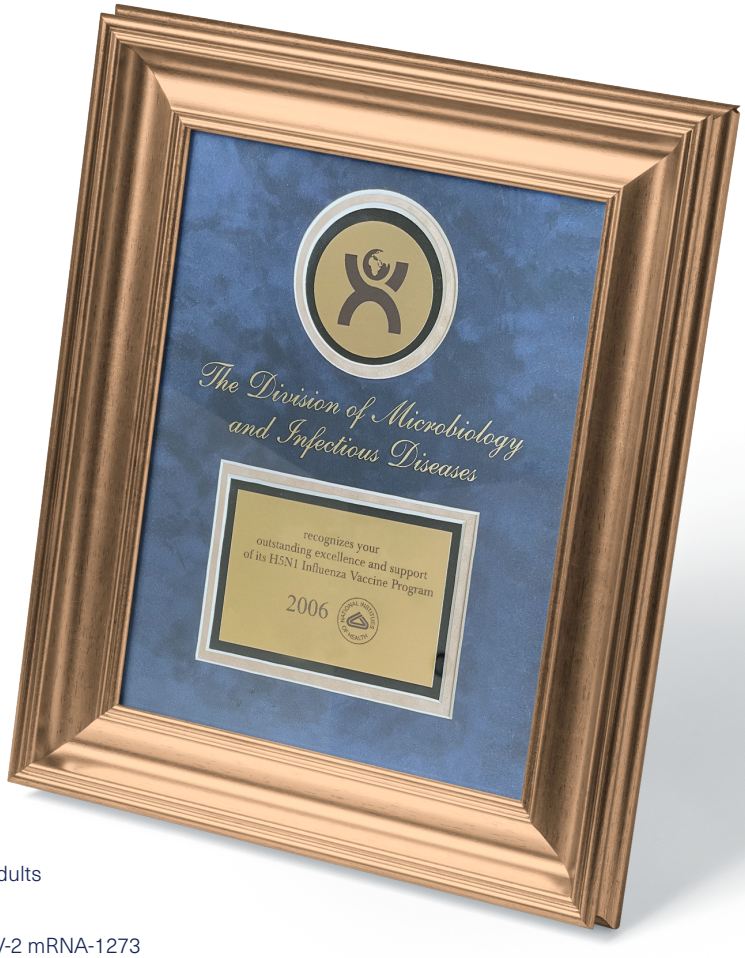
- During the 2014 Ebola outbreak in West Africa, Emmes supported multiple trials for Ebola vaccine candidates and provided data management, statistical, and monitoring support and on-site training in Sierra Leone amid the Ebola epidemic.

- Emmes has provided data management, clinical monitoring, and statistical support to the AIDS Vaccine Evaluation Group (AVEG) for 50 clinical trials, beginning in 1988, to the International AIDS Vaccine Initiative (IAVI) for more than 40 trials from 2000 to present day, and to the Rockefeller foundation beginning in 2009.

Recognition of excellence

NIAID Merit Award in recognition of outstanding performance in response to the Ebola outbreak, expediting clinical development of a promising vaccine candidate, providing expert consultation to internal, external, and international partners.

DMID recognition for outstanding excellence and support of its H5N1 Influenza Vaccine Program.



References

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To learn more about our robust pandemic experience, please visit
www.emmes.com/vaccines-and-Infectious-diseases

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