



USAMRDC COVID-19 Effort Details and Progress



Moving the field forward

USAMRDC offers the capability and capacity to support a whole-of-government approach to accelerate the development of a COVID-19 vaccine and improve COVID-19 testing by leveraging its unique RDA laboratory and product management skill sets and facilities. MRDC provides coronavirus expertise, vaccine clinical trial expertise, a global clinical trial network, regulatory support, and a College of American Pathologist-accredited clinical diagnostic program.

We have extensive capabilities and an international research infrastructure already in place that allows our scientists to anticipate and develop countermeasures against emerging infectious diseases

BG Michael Talley
Commanding General, USAMRDC



Vaccine Development



- ▶ Produced the most detailed atomic-level view of the SARS-CoV-2 spike protein receptor binding domain, which is the part of the virus that binds to the lungs. This has been critical to vaccine discovery and development efforts as it provides a resource map for the field in rationale vaccine design.
- ▶ USAMRDC is in full support of Operation Warp Speed, a coordinating effort to accelerate COVID-19 vaccine development.
- ▶ Down-selected a vaccine candidate from multiple prototypes based on an approach that has shown promise for other respiratory viruses, such as influenza.
- ▶ Performed foundational studies to establish validated small and large animal models for testing vaccine candidates and therapeutics in development. Animal efficacy testing will be done in parallel with human safety testing to accelerate vaccine development efforts.
- ▶ Phase I clinical trials for a vaccine candidate remain on track to begin Winter 2021 to evaluate safety of the candidate vaccine.
- ▶ While USAMRDC is working to develop and test a vaccine, the Command is also partnering with government, academia, and industry to identify opportunities to leverage USAMRDC's full range of vaccine development competencies in support of accelerating the most promising vaccine candidates.

Diagnostics



- ▶ USAMRDC researchers are developing a step-wise algorithm (test or series of tests) to diagnose symptomatic individuals, screen for immune status in training and operational settings, and utilize in medical countermeasure clinical trials.
- ▶ USAMRDC provides technical advice regarding new testing systems.
- ▶ Three USAMRDC experts are advising the White House COVID-19 Task Force on the development of a national strategy for high throughput genetic and antibody testing.
- ▶ Developing tests to confirm virus clearance, which will inform critical return-to-duty or continued isolation decisions.
- ▶ Research efforts to better understand how to measure and interpret testing results started in April and are projected to be completed by 31 Dec 2020.
- ▶ Working with industry partners we are developing and evaluating immunoassays to help determine (1) who is immune and whether their antibody responses are protective, (2) who is not immune and may be at risk of infection (these are good volunteers for vaccine trials), and (3) who has sufficient antibody levels for their blood to be used for treatment (i.e., convalescent plasma).
- ▶ WRAIR is evaluating relevant antibodies for use in a rapid test device for identification of acute SARS-CoV-2 infection in austere, far-forward military environments.
- ▶ The goal is a portable field device with the ability to detect the virus during early stages of infection.
- ▶ The USAMRDC AM WG is coordinating mechanical testing, verification, and validation for 3D-printed swabs and alternative viral transport media for use with EUA-approved diagnostic assays, and the developmental testing and certification of masks with CCDC and NIOSH in order to support EUA applications to FDA.



Treatment



- ▶ **Remdesivir** (Gilead Sciences) was an investigational drug with broad spectrum activity against an array of viruses that recently received EUA status. FDA licensed this drug on 22 OCT. USAMMDA led an Expanded Access treatment protocol for DoD personnel treating 40 DoD personnel.
- ▶ Remdesivir was previously investigated by the DoD for activity against Ebola. Clinical Trials for Remdesivir for COVID treatment are complete and Remdesivir is not considered to be standard of care for hospitalized COVID infected patients.
- ▶ USAMRDC is leading an Expanded Access Investigational New Drug using **Convalescent Plasma** to treat DoD personnel, beneficiaries, and eligible civilians diagnosed with severe or life-threatening COVID-19.
- ▶ Working with industry partners to further mature new antivirals and drugs to combat severe respiratory consequences of COVID. Studies include FDA-regulated Phase 2 efficacy and Phase 1 safety trials for these compounds. These studies are on track to complete by Spring 2021.
- ▶ USAMRDC in partnership with industry used AI and machine learning to screen 40 million drug compounds identifying a few hundred promising drug candidates that are undergoing further testing. We expect the best candidates to enter animal testing by Summer 2021.



*NIID: National Institute of Allergy and Infectious Diseases
CCDC: U.S. Army Combat Capabilities Development Command
NIOSH: National Institute for Occupational Safety and Health*