USAMRDC COVID-19 Capabilities

U.S. Army Medical Research and Development Command provides subject matter expertise on standardization of data elements and research activities, best practices, identifying gaps, prioritizing activities and strategy development to support the whole-of-government approach to combating COVID-19.

> "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***

Partners

- Department of Health and Human Services
- Biomedical Advanced Research Development Authority
- Centers for Disease Control and Prevention
- National Institutes of Health
- U.S. Food and Drug Administration
- Vaccine Research Center
- Department of Homeland Security
- Academia
- Industry: Merck, GSK, Sanofi, AstraZeneca, Gilead Sciences…

USAMRIID

- Expert testing and evaluation of leading candidate vaccines and drugs to support FDA submissions under the Animal Rule
- World-class aerobiology capability for animal efficacy studies with BSL-3 and BSL-4 pathogens
- One of only 3 diagnostic National Laboratories in the CDC Laboratory Response Network
- Decades of experience tracking and supporting disease outbreaks

WRAIR

- Extensive expertise developing new vaccines, therapeutics, and diagnostics for military-relevant and emerging infectious diseases
- Robust drug discovery pipeline
- Resources include a Pilot Bioproduction Facility for small-scale manufacturing, the Clinical Trials Center for early stage human testing, disease surveillance capabilities, and overseas research laboratory network for research and clinical trials

TATRC

- Expertise to build a "virtualized" hospital leveraging telemedicine, AI, robotics, and automation technology
- Capability to create a Soldier health monitoring system via smartphones and wearables to provide Commanders with timely situational awareness

USARIEM

- Evaluates the use of technologies and other wearable systems, including USARIEM's ECTemp algorithm, to detect key early symptoms and monitor body temperature for fever
- DoD lead for one of the subgroups under the Mass General Brigham Center for COVID Innovation, Direct to Consumer Mobile Health Working Group, addressing the monitoring of service providers and patients in disaster scenarios

WRAIR USAMRD Georgia

- Provides laboratory support throughout the EUCOM AOR

USAARL

- DoD lead for MEDEVAC airworthiness test and evaluation of medical equipment
- Dedicated rotary-wing research platforms for rapid-response, in-flight performance testing
- Long history of evaluating protective equipment

WRAIR USAMRD Africa

- Completes numerous clinical trials for vaccines and therapeutics to protect against infectious disease
- Supports efforts to monitor/combat diseases
- Serves as a hub for research and surveillance sites in seven African countries

USAISR

- Blood ma… …t and blood products rese… …ertise to potentially suppor… …19 convalescent plasma s…
- Research spaces converted to ICU to care for COVID-19 patients

WRAIR AFRIMS

- Completes large-scale clinical trials for a range of disease countermeasures contributing to product licensure
- Participates in the discovery, development, and testing of FDA-approved antimalarial drugs
- Conducts large disease surveillance and cohort studies in at-risk populations throughout Southeast Asia

WRAIR USAMRD West

- Conducts psychological research studies and provides behavioral health assessments for COVID-19

USAMMDA

- Identifies and evaluates USAMRDC medical products and cutting-edge technology to lead development and delivery of validated, FDA-approved medical solutions
- Provides rapid operationalization of investigational or EUA products when no FDA-approved or feasible solution exists
- Conducts technology maturation, engineering, and manufacturing development, production, and worldwide deployment of medical solutions

USAMRD: U.S. Army Medical Research Detachment
AFRIMS: Armed Forces Research Institute of Medical Sciences

USAMRDC COVID-19 Response

Protect

Objective: Expedite development of a safe, effective vaccine, and other preventive measures against COVID-19

- **Vaccine Development:** Spike ferritin nanoparticle (SpFN) vaccine candidate started clinical testing in humans April 2, 2021. The phase 1 study is being conducted at WRAIR's Clinical Trials Center.
- Actively working 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.
- 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 lungs. This has been critical to vaccine discovery and development efforts as it provides a resource map for the field in rational vaccine design.
- **Animal Model Development:** Rapidly developed small and large animal models for testing candidate vaccines and therapeutics. Animal efficacy testing is ongoing with preparations for human safety testing to accelerate vaccine development efforts.
- **Monoclonal Antibodies**: Partnering with government and industry to develop monoclonal antibodies as potential treatments for COVID-19 infection. These antibodies are proteins engineered to optimize the body's natural immune response by preventing the virus from entering and replicating within human cells.
- **Protective Equipment:** Testing portable isolation units, masks, and other protective equipment to determine airworthiness for MEDEVAC and other flight operations and leading an inter-service group, the USAMRDC Additive Manufacturing (AM) Working Group (WG), to assist with the development, manufacturing, testing, and regulatory submission of Personal Protective Equipment (PPE) seeking FDA Emergency Use Authorization.
- **Federal COVID Response (FCR) Support:** We are supporting the whole-of-government response to COVID-19. USAMRIID is testing monoclonal antibodies in animal models in direct support of the FCR therapeutics group. MRDC also supports FCR in procurement, regulatory, legal and other key areas.

USAMRDC COVID-19 Response

Detect

Objective: Develop a validated test or series of tests for COVID-19 diagnostic, transmissibility, exposure, and/or recovery decisions.

- Evaluating relevant antibodies for use in developing a rapid, portable test device to detect the virus during early stages of infection in austere, far-forward military environments.
- 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.
- 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 are underway.
- Working with industry partners, 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, and (3) who has sufficient antibody levels for their blood to be used for convalescent plasma.
- USAMRDC scientists have developed a way to screen thousands of samples in a single pooled tube using next generation sequencing technology. This has the potential to greatly influence the ability to assess readiness and illness contact tracing.

USAMRDC COVID-19 Response

Treatment

Objective: Develop safe, effective, and accessible treatments for those diagnosed with COVID-19.

- 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 refine 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 and remain ongoing.
- USAMRDC, in partnership with industry, used AI and machine learning to screen >41 million drug compounds, identifying a few hundred promising drug candidates that are undergoing further testing. The best candidates are undergoing animal testing. The entire effort will be complete by September 2021.
- Clinical Trials for Remdesivir for COVID treatment are complete and Remdesivir is considered to be standard of care for hospitalized COVID infected patients. Remdesivir was previously investigated by the DoD for activity against Ebola.
- NETCCN-TiDE COVID Efforts: During COVID Operations, the Telemedicine and Advanced Technology Research Center delivered critical care expertise and increased capabilities to the point of need by leveraging telemedicine. TATRC is transitioning to solutions focused on “all hazards” approach through continued collaboration with the Health and Human Services Assistant Secretary for Preparedness and Response. Data learned during large scale natural disaster may be beneficial for understanding casualty care during Large Scale Combat Operations (LSCO). Phase II work began in June and will continue through September 2022 including scaling, device remote control, data interoperability/analysis/visualization, command and control, learning, and algorithm development.