U.S. Army Medical Research and Development Command (USAMRDC)

COVID-19 Common Operational Picture

COLLABORATORS

DHHS
CDC
NIH
BARDA
FDA
Large Corporations
VRC
Small Businesses
DHS
Universities
Non-Profits
DOS
NGOs

MECHANISMS

Animal Models
Computer Modeling
Manufacturing Process Development
CRADAs
Clinical Trials
Medical Simulation
Discovery Science
EUAs/ EA

PREVENT • DETECT • TREAT

Vaccines • Rapid Diagnostics • Drugs • Monoclonal Antibodies • Convalescent Plasma • Behavioral Health • Aircrew Performance • Portable Isolation • Telemedicine

USAMRDC

Global Surveillance Network • Laboratory Response Network

Combatant Commands • DOS • Interagency • Academia • Industry • International Partners

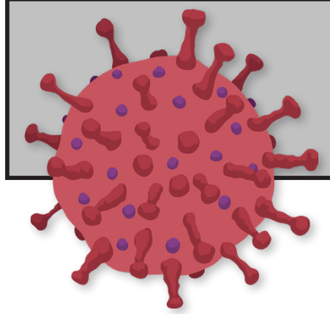
USARIEM
WRAIR
HQ, USAMRDC
USAMRIID
USAMMDA
TATRC
USAISR
USAARL
USAMRD-W
USAMRD-G
USAMRD-A
AFRIMS

Threat Stand-Off

Department of Defense

National Security

EUA/EA: Emergency Use Authorization/Emergency Assistance
CRADA: Cooperative Research and Development Agreement



USAMRDC COVID-19 Response

USAMRDC is leading research efforts to Prevent, Detect, and Treat COVID-19.

Walter Reed Army Institute of Research (WRAIR), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), U.S. Army Medical Materiel Development Activity (USAMMDA), U.S. Army Institute of Surgical Research (USAISR), U.S. Army Aeromedical Research Laboratory (USAARL), U.S. Army Research Institute of Environmental Medicine (USARIEM), and Telemedicine and Advanced Technology Research Center (TATRC) are applying existing field-leading research, a global research network, and established partnerships with industry and academia to support the whole-of-government response to COVID-19.

PREVENT

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

Approach:

- **Vaccine Development:** WRAIR's vaccine candidate will move forward into initial clinical testing in humans. USAMRDC is actively working with the National Institutes of Health and industry partners to evaluate other promising vaccines.
- **Animal Model Development:** USAMRIID is evaluating animal models to identify a suitable correlate of human disease to test COVID-19 medical countermeasures.
- **Monoclonal Antibodies:** To help protect (and potentially treat) cells from COVID-19 infection, WRAIR and USAMRIID are partnering with government and industry to develop monoclonal antibodies (man-made proteins engineered to optimize the body's natural response to fight infection by preventing the virus from entering and replicating within human cells).
- **Protective Equipment:** USAARL is testing portable isolation units, masks, and other protective equipment to determine air worthiness for MEDEVAC and other flight operations. USAMMDA leads an inter-service group, the USAMRDC Additive Manufacturing (AM) Working Group (WG), to assist with the development, manufacturing, testing, and regulatory submission of N95 respirators seeking FDA Emergency Use Authorization.

DETECT

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

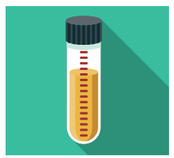
Approach:

- **Diagnostics:** USAMRDC is collaborating with government, academia, and industry to quickly identify, develop, and validate diagnostic capabilities to detect the virus in a high throughput capacity as well as research tests to support medical countermeasure development. USAMRDC also assists with the manufacturing, testing, and regulatory submission of 3D-printed swabs and alternative Viral Transport Media to the FDA.
- **Clearance Tests:** Researchers are developing assays that confirm clearance of the virus, which are critical for making return-to-duty or continued isolation recommendations.
- **Immunoassays:** Along with multiple government and industry partners, USAMRDC is developing/evaluating immunoassays to detect COVID-19 antibodies, which will inform exposure and immunity status.
- **Point-of-Care, Rapid Testing:** WRAIR is evaluating antibodies for use in a point-of-care, rapid test device to identify COVID-19 infection in resource-constrained environments.

TREAT

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

Approach:



- **Remdesivir:** USAMMDA is offering patients diagnosed with moderate to severe COVID-19 an additional treatment option using Remdesivir (Gilead Sciences).
- **Convalescent Plasma:** USAMRDC is offering patients with serious/life-threatening infections plasma from those who have recovered from COVID-19.
- **Monoclonal Antibodies:** In addition to preventative aspects, USAMRDC and industry partners are developing monoclonal antibodies that can neutralize the virus while also fighting harmful inflammation.
- **Drug Discovery:** WRAIR and USAMRIID are collaborating with industry partners on drug discovery using cutting-edge artificial intelligence and machine-learning techniques.
- **Small Molecules:** WRAIR and USAMRIID are screening for additional therapeutics.
- **Medical Equipment:** USAMMDA, in coordination with the Army logistics community, is filling shortages of needed medical equipment for deploying medical units.
- **Telecritical Care:** TATRC is collaborating to develop a National Emergency Telecritical Care Network to provide virtual care in global emergency situations, at the point of need.

USAMRDC ensures that all research strictly conforms to all regulatory guidance. Oversight and coordination are provided by:

- Office of Regulated Activities
- Office of Research Protections
- Office of Regulated Quality Activities
- Staff Judge Advocate Office
- Sponsor's Authorized Representative (FDA)

Research efforts are also supported by other offices and organizations within the Command, including:

- Strategic Communications
- Resource Management
- U.S. Army Medical Research Acquisition Activity

Research Grants with Academia, Industry, and Other Partners:

- The Congressionally Directed Medical Research Program's Peer Reviewed Medical Research Program released two Program Announcements for COVID-19 research for up to $75 million.

Business Management Support:

- The Office of Research and Technology Applications coordinates all intellectual property licensing developing CRADAs, Material Transfer Agreements, Interagency Agreements, Nondisclosure Agreements, and other tech transfer transactions.

USAMRDC COVID-19 Other Transaction Authority (OTA):

Medical Technology Enterprise Consortium

- Through OTAs, USAMRDC can move quickly and have the flexibility to enable awards that involve complex collaborations with multiple companies and government laboratories working together to further develop and implement solutions.

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USAMRDC COVID-19 Capabilities

U.S. Army Medical Research and Development Command competencies and capabilities are supporting the U.S. Government response effort through the Interagency Medical Countermeasures Task Force, led by the Department of Health and Human Services. USAMRDC 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

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

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

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

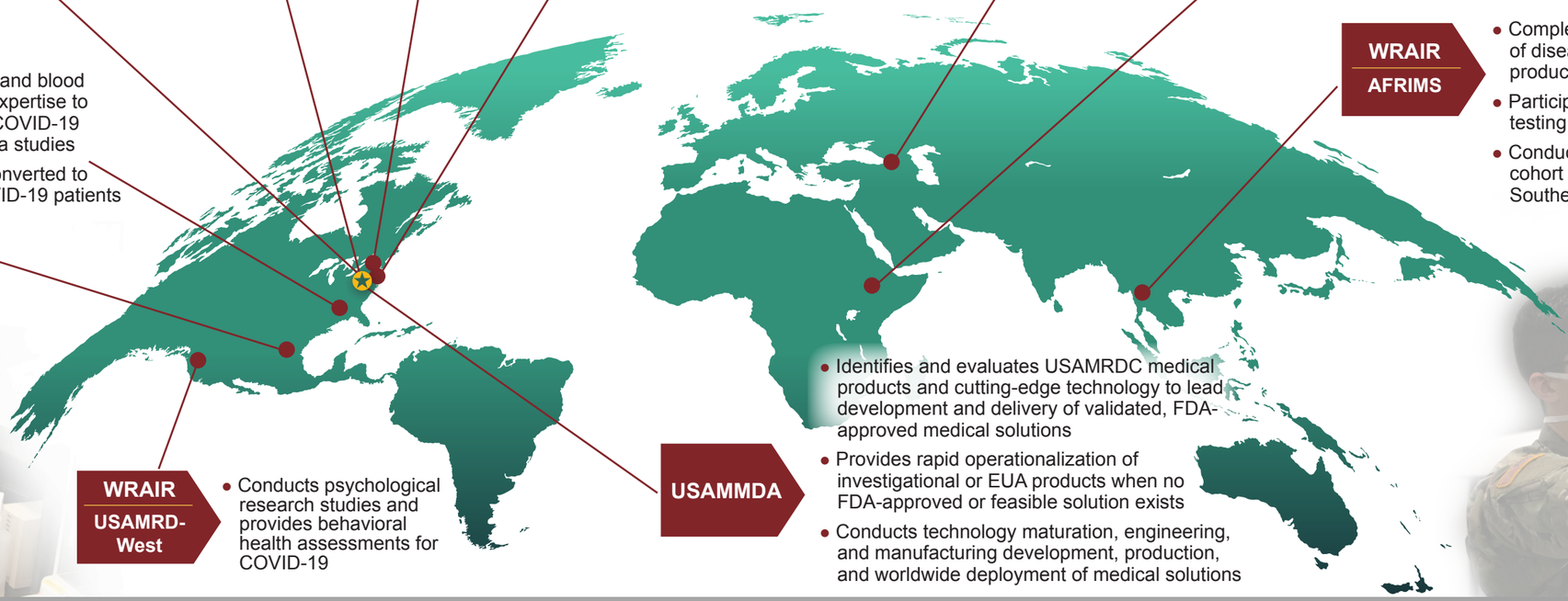
WRAIR / USAMRD-Georgia
- Provides laboratory support throughout the EUCOM AOR

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 management and blood products research expertise to potentially support COVID-19 convalescent plasma studies
- 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

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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 both WRAIR and USAMRIID's unique research laboratory skill sets and facilities. The Command provides coronavirus expertise, vaccine clinical trial expertise, a global clinical trial network, regulatory support, and a College of American Pathologist-accredited, clinical diagnostic program.

Vaccine Development

- WRAIR 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 acclerate COVID-19 vaccine development.
- WRAIR down-selected a vaccine candidate from multiple prototypes based on an approach that has shown promise for other respiratory viruses, such as influenza.
- Researchers at USAMRIID are performing foundational studies to establish validated small and large animal models for testing not only WRAIR's vaccine candidate but multiple vaccines 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 WRAIR's vaccine candidate remain on track to start screening potential human subjects in July, with the goal of starting vaccinations in September 2020 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.

Testing

- 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.
- WRAIR is 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.
- WRAIR, USAMRIID, and industry partners 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.

Expanded Access Treatment Protocols

- **Remdesivir** (Gilead Sciences) is an investigational drug with broad spectrum activity against an array of viruses that recently received EUA status. USAMMDA is leading an Expanded Access treatment protocol for DoD personnel with moderate to severe COVID-19.
- In laboratory studies conducted prior to the COVID-19 outbreak, researchers at the University of North Carolina and Vanderbilt University found that Remdesivir had potent activity against a wide variety of coronaviruses similar to SARS-CoV-2.
- Remdesivir was previously investigated by the DoD for activity against Ebola. It is currently being evaluated in a NIAID-sponsored Adaptive Clinical Trial for hospitalized patients as well as other trials sponsored by Gilead.
- Remdesivir's target is the viral RNA-dependent RNA polymerase needed for viral replication.
- As of 15 May 2020, there are 23 military treatment facilities globally ready to provide Remdesivir to treat COVID-19 patients in USAMMDA's treatment protocol.
- 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.

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

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For more info, visit: https://mrdc.amedd.army.mil/index.cfm/resources/covid-19