

WHITE PAPER



THE BENEFITS OF WORKING WITH MILITARY POPULATIONS IN CLINICAL TRIALS

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INTRODUCTION



CLINICAL TRIALS
CAPABILITIES



GENEVA'S CLINICAL TRIALS EXPERTISE

Geneva has over 25 years of experience in advancing clinical trials within the Department of Defense (DoD)'s network of military treatment facilities (MTFs). Geneva is fully integrated within the Military Health System and delivers an average of 75 open industry-sponsored studies at any given time, with an estimated 25 new industry-sponsored studies per year.



Clinical trials are essential to medical innovation, improved patient outcomes, and the generation of invaluable scientific data. However, they are typically resource-intensive and require adequate recruitment and retention rates to achieve sufficient evidence and minimize bias. The U.S. Food and Drug Administration (FDA) states that overall, [few people sign up for and participate in trials](#), and those who do participate aren't always representative of the U.S. population.

The U.S. military population, made up of active duty personnel, retirees, their families, and veterans, is a highly diverse and compliant patient population that offers specific benefits to clinical trials not always available in civilian populations.

Military populations are representative of the diseases and conditions that occur in the civilian community as well as those that are unique to members of military service. Service members have acute and chronic health needs which they experience during their service and long after leaving the military. According to a [study examining the clinical trials](#)

[registry](#), the top five conditions of interest most conducted in clinical trials with service members were: post-traumatic stress disorder, traumatic brain injury, amputations, burns, and ocular injuries/disorders.

Compared to their civilian counterparts, military service members offer an unusually mobile, transient, and culturally unique research population. Compared to the civilian sector, the military has a high acceptance rate for clinical trials and offers access to large populations that are critical for studies [aiming to enroll 500 or more participants](#).

In addition to a highly compliant and diverse voluntary patient population, there are additional benefits. Working with military populations in clinical trials offers investigators and sponsors streamlined efficiency, such as:

- Electronic health records [within one healthcare system](#)
- Onsite primary care, specialty care, and auxiliary services at all MTFs
- A single clinical trial agreement that supports the involvement of several different MTFs within the U.S.

ABOUT THE GENEVA FOUNDATION

Geneva is a 501(c)3 non-profit organization that advances military medicine through innovative scientific research, exceptional program management, and a dedication to U.S. service members and veterans, their families, and the global community.

Established in 1993, Geneva builds partnerships, advancing military medical innovations through collaborations with world-renowned research professionals, federal agencies, academic entities, and industry partners. Geneva facilitates phase II-IV clinical trials at MTFs nationwide. Geneva's connections to pharmaceutical, device, and biotech companies present unique partnership opportunities.



WHY DIVERSITY MATTERS

Importance of Recruitment, Retention, and Diversity in Clinical Trials

Optimal participant recruitment and adequate retention rates are essential to ensuring meaningful results in any clinical trial, but participation overall is especially low for certain populations, including adults age 75 or older and people from certain racial and ethnic groups, according to the FDA.

Veterans see themselves as more disciplined (84%) and patriotic (71%) than those who have not served in the military. Participant compliance is essential to reduce study delays and improve outcomes of clinical trials.

It is also important for clinical trials to have participants of different ages, genders, races, and ethnicities. When clinical trials include diverse participants, the study results may have a much wider applicability. Studies have shown that there can be important differences in how people of diverse groups respond to medical products. According to Pfizer, genetics, gender, weight, ethnic origin, even geographic location – all of these may play a role in treatment efficacy and safety. Fortunately, the military community is well-represented in these key requirements.

Diversity in the U.S. Military

As the country has become more racially and ethnically diverse, so has the U.S. military. Racial and ethnic minority groups made up 40% of DoD active-duty military in 2015, up from 25% in 1990. Hispanics are the fastest growing minority population in the military – a shift that aligns with larger demographic trends in the U.S.

The active-duty military population has also grown older, according to the Pew Research Center. Roughly two-thirds of all DoD active-duty military personnel were ages 30 or younger in 2015. One-in-ten (9%) were older than 40, representing a steady increase in age over the last 40 years.

DIVERSITY RESULTS HIGHLIGHT: OPERATION WARP SPEED*

Geneva was selected as a subcontractor under prime contract research organization (CRO) Pharm-Olam to administer phase III clinical trials at 6 MTFs for two lead COVID-19 vaccine candidates being developed under Operation Warp Speed (OWS). OWS is a partnership created to deliver safe and effective doses of a COVID-19 vaccine by January 2021. *OWS was renamed COVID-19 Response Operation in January 2021.

AstraZeneca

Geneva enrolled 1,447 participants at five MTFs

- 24% 65+ years and older
- 55% had co-morbidities
- 10% AA/Black
- 11% LatinX
- 72% Caucasian

Novavax

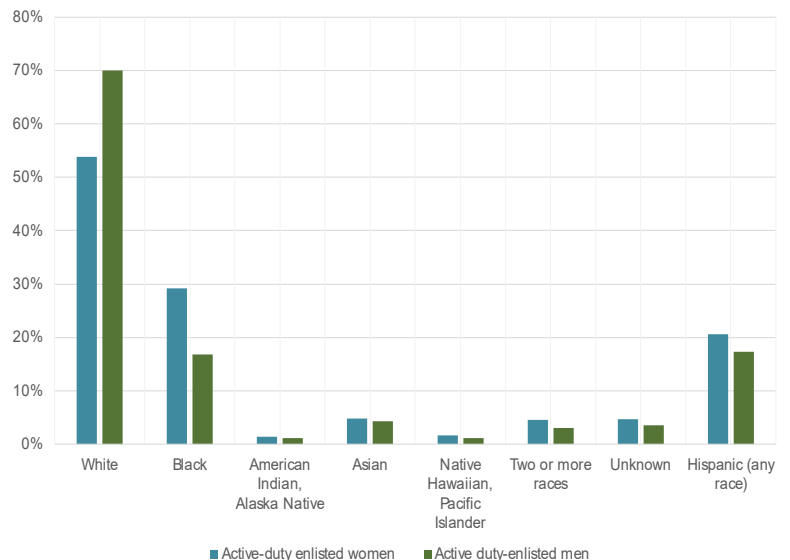
Geneva enrolled 240 participants at one MTF

- 30% older than 65
- 25% AA/Black
- 5% Asian
- 8% LatinX
- 68% Caucasian

BREAKDOWN OF RACE AND ETHNICITY IN THE MILITARY

Fig.1 Distribution of active-duty enlisted women and men in the U.S. military in 2018, by race and ethnicity

Source: <https://www.statista.com/statistics/214869/share-of-active-duty-enlisted-women-and-men-in-the-us-military/>



REDUCING THE REGULATORY BURDEN



"By knowing what sponsors fear most, we can knock months off of the process and help keep clinical trials on time and in budget."



GENEVA'S CLINICAL TRIAL EXPERTISE

- Full lifecycle management of clinical trials
- Negotiation and execution of all agreements
- Development and management of study financials
- Lifecycle management of regulatory package by dedicated, skilled regulatory professionals
- Experience with DoD, FDA and HHS requirements
- Provision of experienced research personnel
- Ongoing project management oversight
- Engagement in subject enrollment and study conduct
- Compliance with Good Clinical Research Practices (GCPs) and all other applicable regulations

There is no front door to conducting clinical trials in the military. Fortunately, that's where Geneva excels.

Research supported by the DoD or recruitment of DoD personnel for clinical trials requires compliance with additional federal regulations, directives, and instructions.

The Institutional Review Board (IRB) process is stricter in DoD facilities. Geneva's experience in navigating the stricter processes can alleviate the pain of bureaucracy. By working under a single Cooperative Research and Development Agreement (CRADA), Geneva can also support the involvement of several MTFs within the U.S. under a single negotiated CRADA, thus accelerating the agreement process.

Industry-Sponsored Research

Geneva partners with industry to advance medicine for the benefit of the global community. The Geneva team consists of experienced leaders who provide on-time, quality data in accordance with the sponsor's expectation and applicable governing regulations. Geneva has experienced staff who are dedicated to conducting clinical trials at MTFs nationwide, and who facilitate collaborative research between investigators, collaborators, and sponsors.

"By knowing what sponsors fear most, we can knock months off of the process and help keep clinical trials on time and in budget," said Elissa Thomas, Geneva's Associate Director, Office of Research Management.

Geneva is currently managing industry-sponsored clinical trials at eight MTFs in therapeutic indications including: solid tumors, non-small cell lung cancer, Crohn's disease, cirrhosis, non-alcoholic steatohepatitis (NASH), follicular lymphoma, bladder cancer, breast cancer, colorectal cancer, coronary artery disease, neoplasia, carcinoma, opioid reduction, maternal RSV, anemia, back pain, and osteoarthritis.

Geneva's Clinical Trials for COVID-19 Research

- NIH-2 ACTIV Network
- NIH-4 ACTIV Network
- Operation Warp Speed
- Vaccine Effectiveness and Immune Response of SARS-CoV-2 Vaccines in Active Military Personnel

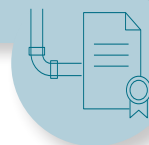


WORKING WITHIN THE MILITARY HEALTH SYSTEM



GENEVA CLINICAL TRIAL STATS

- Geneva has 85+ years of combined clinical trials experience among corporate staff
- Geneva executed 314 bookings from 2014-2020
- 77% of Geneva's clinical trials coordinators (CRC) are certified
- Geneva defers to central IRBs at most sites



The [DoD](#) is the largest federal sponsor of research and development (R&D), with the majority of R&D funded through DoD [Science and Technology](#). According to [clinicaltrials.gov](#), there are 141,706 clinical trials underway in the U.S. as of 30 April 2021. Out of those trials, 1,543 have the word military in the study topic with an additional 1,549 including Army medicine, 576 including Air Force medicine, and 71 involving Navy medicine.

In addition to working with industry sponsors not facilitated by the Military Health System (MHS), Geneva is leading, collaborating, or sponsoring 17 of these currently active, ongoing, or completed clinical trials through federal contracts and grants.

Geneva also collaborates with industry sponsors and large government-led initiatives such as Operation Warp Speed, and National Institutes of Health (NIH)-led Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership to speed the development of the most promising treatments and vaccines.

Geneva has 27+ years of experience working with DoD sponsors, including:

- Congressionally Directed Medical Research Program (CDMRP)
- Defense Advanced Research Projects Agency (DARPA)
- Defense Threat Reduction Agency (DTRA)
- Natick Contracting Division
- TriService Nursing Research Program (TSNRP)
- U.S. Army Medical Materiel Development Activity (USAMMDA)
- U.S. Army Medical Research & Development Command (USAMRDC)
- Uniformed Services University (USU)

Other key sponsors supporting Geneva research:

- National Institutes of Health (NIH) including NCATS, NCI, NIAID, NIAMS, NIBIB, NIDCD, NIEHS
- Centers for Disease Control (CDC)
- Medical Technology Enterprise Consortium (MTEC)
- National Aeronautics and Space Administration (NASA)

Thank you to all those who have supported Geneva's research and to those who have conducted and participated in clinical trials. We are grateful to everyone who made these clinical trials possible.



CURRENT GENEVA-LED TRIALS*

*according to clinicaltrials.gov as of July 2021

Status (as of July 2021)	Study Title	Conditions	Locations
<ul style="list-style-type: none"> Sponsor Recruiting 	Battlefield Acupuncture for Low Back Pain	<ul style="list-style-type: none"> Low Back Pain Chronic Low Back Pain 	Malcom Grow Medical Clinics and Surgery Center, Andrews Air Force Base, MD
<ul style="list-style-type: none"> Sponsor 	The Prevalence of Nonalcoholic Fatty Liver Disease (NAFLD) in Adults	<ul style="list-style-type: none"> Non-Alcoholic Fatty Liver Disease Non-Alcoholic Steatohepatitis 	Brooke Army Medical Center, Fort Sam Houston, TX
<ul style="list-style-type: none"> Sponsor Recruiting 	The Prevalence of Nonalcoholic Fatty Liver Disease (NAFLD) in Pediatric Patients	<ul style="list-style-type: none"> Steatohepatitis, Nonalcoholic Hemosiderosis Overweight Adolescents Obesity, Childhood Liver Steatosis 	Brooke Army Medical Center, Fort Sam Houston, TX
<ul style="list-style-type: none"> Collaborator Withdrawn 	The Use of the PoNS™ Device in the Treatment of Blunt and Blast Induced Vestibular Disorders	<ul style="list-style-type: none"> Hearing and Vestibular Disorders 	Naval Medical Center-San Diego, San Diego, CA
<ul style="list-style-type: none"> Investigator Completed 	Comparing Aerobic to Resistance Training in Recovery From Cancer	<ul style="list-style-type: none"> Neoplasms 	Brooke Army Medical Center, Fort Sam Houston, TX
<ul style="list-style-type: none"> Collaborator 	External Immobilization Compared to Limited Immobilization Using a Novel Real-time Localization System of the Prostate	<ul style="list-style-type: none"> Prostate Cancer 	Madigan Healthcare System, Tacoma, WA
<ul style="list-style-type: none"> Collaborator 	Reduced Planning Target Volume (PTV) Margins for the Treatment of Prostate Cancer Using the Calypso 4D Localization System	<ul style="list-style-type: none"> Prostate Cancer 	Madigan Healthcare System, Tacoma, WA
<ul style="list-style-type: none"> Collaborator Completed 	Comparing Virtual Reality Exposure Therapy to Prolonged Exposure	<ul style="list-style-type: none"> Stress Disorders Post-Traumatic Stress Disorder 	Womack Clinical Psychology Service, Fort Bragg, NC
<ul style="list-style-type: none"> Collaborator Active, not recruiting 	TMS for Suicidal Crisis in Active Duty SMs	<ul style="list-style-type: none"> Suicide Suicidal and Self-Injurious Behavior Suicidal Depression 	Eisenhower Army Medical Center, Augusta, GA
<ul style="list-style-type: none"> Collaborator 	A Head-to-head Comparison of Virtual Reality Treatment for Post Traumatic Stress Disorder	<ul style="list-style-type: none"> Post Traumatic Stress Disorder 	Camp Pendleton, Camp Pendleton, CA Naval Medical Center San Diego, San Diego, CA
<ul style="list-style-type: none"> Investigator Enrolling by Invitation 	Evaluating the Diagnostic Performance of ACS Using NIRS in Traumatized Lower Extremities	<ul style="list-style-type: none"> Compartment Syndrome of Leg 	Brett A. Freedman, Col, MD, Rochester, MN
<ul style="list-style-type: none"> Collaborator Completed 	The Effects of Mogroside Sweetener on Viral Load in Treatment Naive Genotype 1 (GT 1) Subjects CHC	<ul style="list-style-type: none"> Hepatitis C 	Brooke Army Medical Center, San Antonio, TX
<ul style="list-style-type: none"> Collaborator Completed 	Pioglitazone on Viral Kinetics, Cytokines and Innate Immunity in Unsulin Resistant CHC GT1 Subjects	<ul style="list-style-type: none"> Chronic Hepatitis C 	Brooke Army Medical Center, San Antonio, TX
<ul style="list-style-type: none"> Collaborator 	Using Real-Time Functional Brain Imaging to Enhance Recovery From TBI	<ul style="list-style-type: none"> Traumatic Brain Injury Post-Traumatic Stress Disorder 	Carl R Darnall Army Medical Center, Fort Hood, TX
<ul style="list-style-type: none"> Collaborator Completed 	Correlation of Auscultatory Severity of Aortic Stenosis With Trans Thoracic Echocardiography	<ul style="list-style-type: none"> Aortic Stenosis 	Naval Medical Center - San Diego, San Diego, CA
<ul style="list-style-type: none"> Completed 	Study for the Treatment of Significant Steatosis With Xenical Followed by Treatment of Hepatitis C With Pegasys/Copegus	<ul style="list-style-type: none"> Fatty Liver Hepatitis C 	Brooke Army Medical Center, Fort Sam Houston, TX
<ul style="list-style-type: none"> Collaborator Completed 	Virtual Hope Box - Effectiveness of a Smartphone App for Coping With Suicidal Ideation	<ul style="list-style-type: none"> Suicidal Ideation Coping 	Portland VA Medical Center, Portland, OR; National Center for Telehealth and Technology, Tacoma, WA



GENEVA'S CLINICAL TRIALS NETWORK



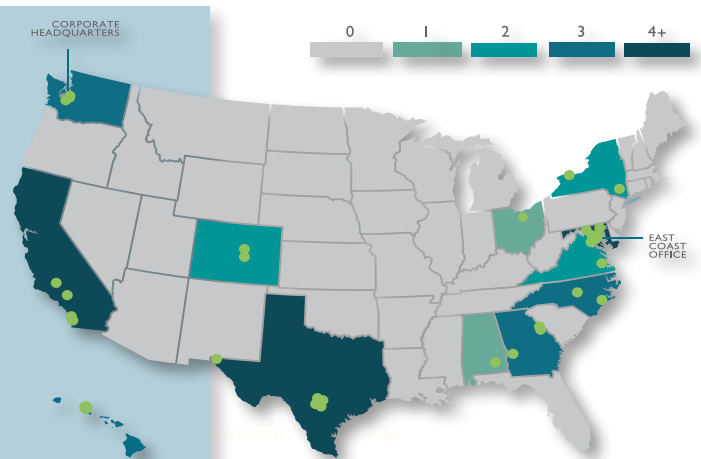
Armed Forces Institute of Medical Sciences
 Brooke Army Medical Center
 David Grant Medical Center
 Eisenhower Army Medical Center
 Evans Army Community Hospital
 Fort Belvoir Community Hospital
 Keller Army Community Hospital
 Landstuhl Regional Army Medical Center
 Madigan Army Medical Center
 Malcom Grow Medical Center
 Marine Corps Air Station Miramar Branch Health Clinic
 National Cancer Institute
 Naval Health Research Center
 Naval Hospital Camp Lejeune
 Naval Hospital Camp Pendleton
 Naval Hospital Twentynine Palms
 Naval Medical Center Portsmouth
 Navy Medical Center San Diego
 Naval Medical Research Center

Navy Trauma Training Center
 Nellis Air Force Base
 Telemedicine and Advanced Technology Research Center
 Tripler Army Medical Center
 Uniformed Services University
 U.S. Air Force Academy Hospital
 U.S. Army Institute of Surgical Research
 U.S. Army Medical Center of Excellence
 U.S. Army Medical Institute of Infectious Diseases
 U.S. Army Medical Research Institute of Chemical Defense
 Walter Reed Army Institute of Research
 Walter Reed National Military Medical Center
 Wilford Hall Medical Center
 William Beaumont Army Medical Center
 Womack Army Medical Center
 Wright Patterson Air Force Base

Geneva is honored to collaborate with more than 50 military treatment facilities and federal laboratories worldwide.

In 2020, Geneva supported over 315 research programs at over 50 military treatment facilities and federal laboratories worldwide. Geneva also worked with over 180 sponsors and collaborators and 187 investigators to advance military medicine.

Geneva's international collaborations include Armed Forces Research Institute of Medical Sciences in Bangkok, Thailand and Landstuhl Regional Army Medical Center in Germany.





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