

CASE STUDY



INSIDE THE SPRINT TO SUPPORT COVID-19 VACCINES

How we helped support the largest vaccine effort in history

OPERATION WARP SPEED - COVID-19 RESPONSE OPERATION SUMMARY



FEDERAL CONTRACTS
CAPABILITIES



GENEVA'S ROLE

- Clinical trials management at military treatment facilities (MTFs)
- Regulatory expertise
- Scientific expertise
- Recruitment of highly skilled medical and technical personnel
- Facilitating the rapid acceleration of research timelines



When the federal government unveiled Operation Warp Speed (OWS) in May 2020, it was “unlike anything our country has seen since the Manhattan Project.” The multi-agency initiative’s central goal - to develop, produce, and distribute 300 million doses of a safe and effective coronavirus vaccine by January 2021 - requires a deep knowledge of science and how to manage complex government operations while navigating a challenging pandemic.

The Geneva Foundation, a non-profit grounded in experience with over 25 years of experience in driving military medical research, responded to the opportunity of a lifetime to join the fight against COVID-19. In September 2020, prime contract research organization (CRO) Pharm-Olam and Geneva were selected by the U.S. Department of Defense (DoD) to support a \$25.7M contract to support a 3,000-patient phase 3 clinical trial for the AstraZeneca (AZ) COVID-19 vaccine clinical trial across five military treatment facilities (MTFs) including Naval Medical Center San Diego, CA;

Brooke Army Medical Center, Wilford Hall Ambulatory Surgical Center, Walter Reed National Military Medical Center, and Fort Belvoir Community Hospital. Additionally in October 2020, Geneva was also awarded a \$5.2M contract to support the Novavax COVID-19 vaccine clinical trial at Fort Bragg.

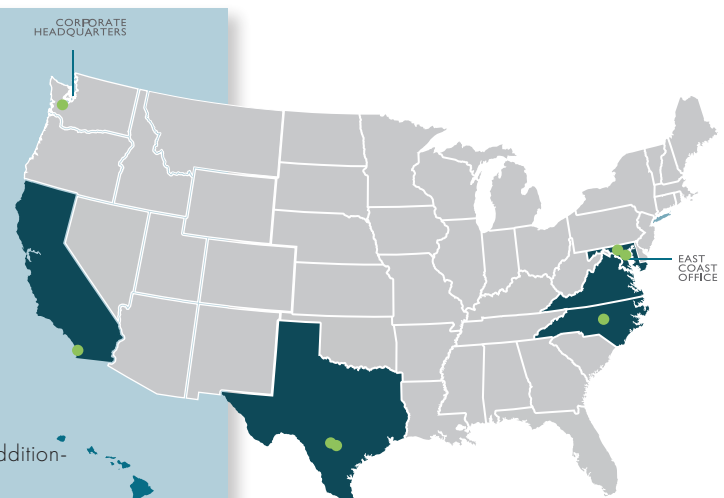
OWS was premised on setting an ambitious goal – one that initially seemed impossible but became increasingly achievable. “We had three weeks to have equipment and materials set up and ready to go,” said Geneva Program Manager Sara Bergeron. “OWS quickly became a 24/7 job for our team.”

In January 2021, OWS was renamed to COVID-19 Response Operation. As of March 2021, Geneva employed 116 employees across the U.S. supporting OWS with 1,720 total participants enrolled across MTFs nationwide. In total, Geneva has 550+ employees worldwide.

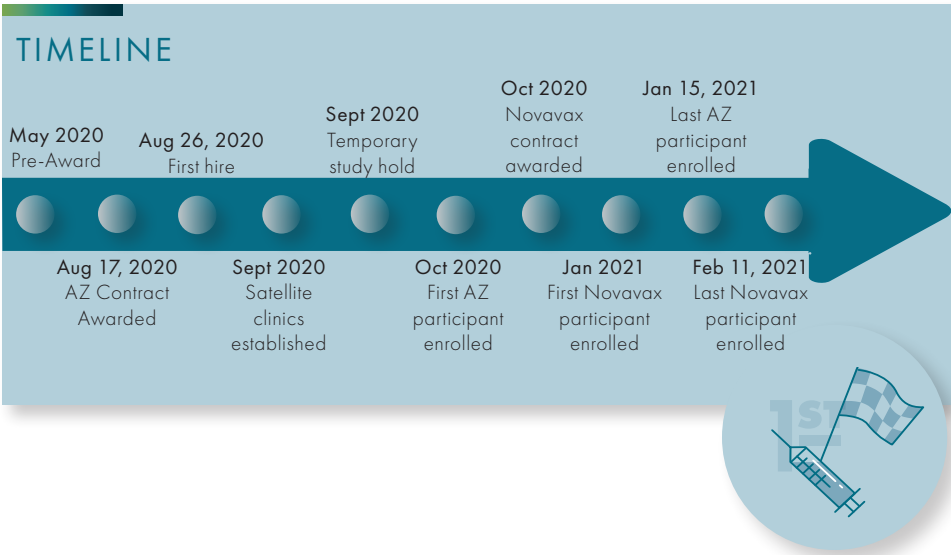
Geneva has advanced COVID-19 vaccines at military treatment facilities including:

- Brooke Army Medical Center
- Fort Belvoir Community Hospital
- Fort Bragg
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- Wilford Hall Ambulatory Surgical Center

Geneva collaborates at 50+ performance sites worldwide in 195+ additional research programs



RISING TO THE CHALLENGE



"Our partnership with prime CRO Pharm-Olam has been outstanding."

Geneva is particularly adept at building teams to support complex research programs.

Sara Bergeron is Geneva's Program Manager assigned to OWS. Program managers put together solution-focused teams to conduct the advanced work and advance research aims. A former Navy Petty Officer with a degree in Molecular Biology, she said the experience has been life changing in many ways. She is inspired by the many colleagues she's worked with supporting the project.

"Our partnership with Pharm-Olam has been outstanding," said Bergeron. "Pharm-Olam's OWS Project Manager Julie Eisenbraun has been the best example of a project manager; I've learned a lot from her that I am already applying at Geneva." As a subcontractor on the award, Geneva proudly works with Pharm-Olam's team to reinforce the OWS endeavor, bringing clinical trials to a diverse and highly compliant military patient population.

Geneva Project Manager Kaitlyn Porter, who works alongside Bergeron, oversees OWS clinical trials in the National Capital Region. Porter uses her degree in Neuroscience and bench-side experience to bridge scientific and technical issues that can arise during complicated Phase 3 trials such as OWS. Project managers also have the challenge of supervising program managers remotely at the military treatment facilities where Geneva is conducting work. "Our teams in the field run the day-to-day operations so it's critical that we have a successful communication plan implemented," said Porter.

Sonya Arzola is one of five Geneva OWS program managers in the field. As Geneva's longest tenured employee, Arzola has more than 20 years of experience at Joint Base San Antonio under her belt to lend to OWS. "With her leadership, she led her staff of 34 people to screen 851 participants in support of OWS, to date – a figure that is unheard of," said her manager Sara Bergeron.

Reporting and invoicing requirements are also essential along with the necessary contract obligations. Geneva Contracts Administrator Evan Strandberg plays a fundamental role in delivering these post-award activity requirements. Strandberg, who says he thrives in fast-paced and collaborative teams such as the Operation Warp Speed team, is responsible for the prompt delivery of federal contract deliverables.

REGULATORY EXPERTISE

Geneva is not a stranger to partnering with CROs to facilitate the successful execution of clinical trials within the military medical system. Geneva's team consists of experienced leaders who provide on-time, quality data in accordance with the sponsor's expectation and applicable governing regulations.

Phase 3 clinical trials are a necessary part of the rigorous scientific process to test the efficacy and safety of a vaccine with a large population sample, including those who are most at-risk of being exposed to the disease, such as the military population.

Elissa Thomas, Sr. Clinical Trials Manager with more than 10 years of experience at Geneva, is Geneva's regulatory and industry sponsored clinical trials go-to person for Operation Warp Speed. Along with Sr. Regulatory Compliance Specialist Allison Northup, the regulatory team ensures that trials comply with FDA and local regulatory requirements.

Geneva's Clinical Trials Capabilities

Geneva partners with biotech firms, pharmaceutical and device manufacturers, and CROs of all sizes in pursuit of Phase II-IV clinical trials within the military medical system. Our strong past performance in infectious diseases research adds value to collaborators when responding to requests for proposals.

BENEFITS OF WORKING WITH MILITARY POPULATIONS

The military medical community offers a diverse research population of active duty personnel, their families, and veterans. Benefits of conducting clinical trials include:

- Highly compliant and diverse patient populations
- Electronic health records
- Onsite primary care, specialty care, and auxiliary services
- Cost-effective trials



RECRUITMENT & PROCUREMENT



POSITIONS RECRUITED FOR OWS

- Administrative assistants
- Clinical program manager
- Clinical project manager
- Clinical research coordinators
- Pharmacy technicians
- Phlebotomists
- Research assistants
- Research laboratory techs
- Research nurses
- Research pharmacists
- Research physician assistant/nurse practitioner



A Record Number of New Hires

Finding and retaining qualified talent is a capability that Geneva provides to all contract services. Recruiting Manager Penina Tinae oversees Geneva's recruiting team and in September and October 2020, the team set a new Geneva record with 104 new hires. There are several types of positions needed to support these trials, including clinical research coordinators, research assistants, and research nurses.

Procurement Services Essential to Research

Supporting and securing an adequate quantity of supplies needed for administration of OWS is an enormous effort. The added challenge of securing personal protective equipment (PPE) in parallel to the tight timelines of getting each facility operational, put Geneva's procurement department to the test.

Geneva's procurement team received an additional 20-30 procurement orders (PO) per week in support of OWS in 2020.

This accounted for 40% of all POs executed and 50% of total amount spent from August through the end of 2020. Geneva Procurement Agent Amy Ceccarelli procured over 17,000 individual items for the project through March 2021.

All Hands On Deck: Team Geneva

The pace and scope of such a vaccine effort are unprecedented in the U.S. and for Geneva. Every department was impacted in some way, from the accounting team who processed additional timecards for 110 additional employees, to the IT team who provided critical technology infrastructure.

Melissa Beale, Director of Geneva's Federal Acquisition Activity Department and charged with overseeing the entire project, is incredibly proud of the work her team has done. "Our team was excited about winning the opportunity, so it seemed easier for them to just jump in and take on whatever was needed. Everyone pitched in to make this happen and it has been successful because of everyone's commitment and dedication."

COLLABORATE WITH GENEVA

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.

Geneva is proud to have over 25 years of experience in delivering full-spectrum scientific, technical, and program management expertise in the areas of federal contracts, federal grants, and industry-sponsored clinical trials. Today, Geneva supports over 320 research programs at over 50 military treatment facilities and federal laboratories worldwide.

For business development opportunities, please contact us at bd@genevausa.org.



With special thanks to:

The researchers who led the site trials

The Departments of Clinical Investigations who provided regulatory support for the trials

The hospital staff, departments, and command leadership who supported the trials

The human participants who selflessly enrolled in the trials

Geneva personnel that led the conduct of the trials

We are grateful to everyone who made these clinical trials possible. Thank you for your commitment, dedication, and unwavering support.



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The future of military medicine. Today.

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