



CASE STUDY



METRC: MAJOR EXTREMITY TRAUMA & REHABILITATION CONSORTIUM

How Geneva advances trauma research through
exceptional program management

IMPROVING QUALITY OF LIFE FOR TRAUMA PATIENTS BACKGROUND



PROGRAM MANAGEMENT
CAPABILITIES



GENEVA'S ROLE

- Provide support for funding under the Department of Defense (DoD)
- Conduct intricate program management to ensure acceleration of regulatory timelines and risk-based reviews
- Recruit highly-trained research and technical personnel
- Provide regulatory expertise, guidance, and compliance
- Conduct clinical studies at five military treatment facilities
- Access to DoD registries and data sharing through REDCap software to support over 17 study protocols



Lessons learned from the battlefield have been fundamental to advancing the treatment of injuries in civilian and military communities. Equally important is the need to further refine these advances in civilian practice, so they are available during future conflicts. The Major Extremity Trauma & Rehabilitation Consortium (METRC) was established in 2009 by the Department of Defense to address these needs.

The Geneva Foundation was established in 1993 and has supported METRC on 17 research programs. METRC is comprised of more than 70 hospitals and is anchored by a coordinating center at Johns Hopkins Bloomberg School of Public Health. Together, METRC and Geneva conduct multi-center clinical research studies relevant to the treatment and outcomes of orthopaedic trauma sustained in the military. The overall goal of METRC is to produce the evidence needed to establish treatment guidelines for the optimal care of the wounded warrior and ultimately improve the clinical,

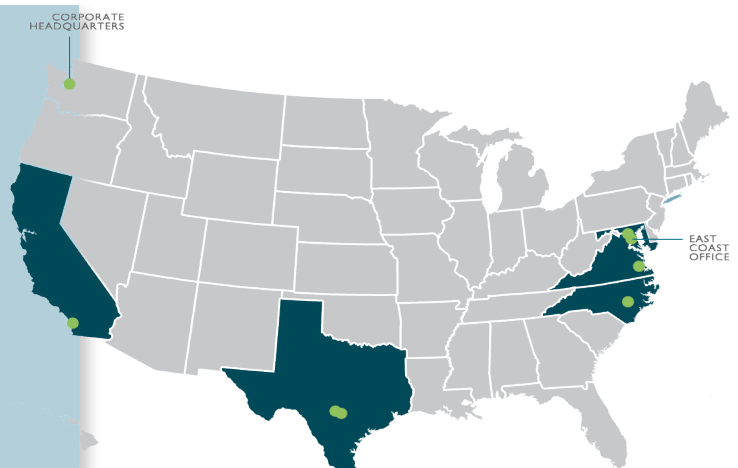
functional, and quality of life outcomes of service members and civilians who sustain severe extremity trauma. In 2016, METRC expanded the scope of its scientific agenda and research study portfolio to include projects which address rehabilitation following traumatic orthopaedic injury. To date, the Consortium has received over \$150M in funding. Geneva manages METRC studies conducted at five military treatment facilities in tandem with the Baltimore-based Coordinating Center (MCC).

METRC has conducted more than 35 clinical studies over the past decade and Geneva has ensured successful participation in 17 of them across five MTFs. Early METRC studies have drawn to a close and results continue to be broadly disseminated among the traumatology community. As METRC looks to the future, it continues to engage its partners in important collaborative research and remains relentlessly dedicated to its core mission.

Geneva has advanced METRC's research at military treatment facilities including:

- San Antonio Military Medical Center
- Naval Medical Center Portsmouth
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- Womack Army Medical Center

Geneva collaborates at 50+ performance sites worldwide in 300+ additional research programs.



RESEARCH SOLUTIONS

"Geneva employees working with METRC have a deep understanding that the work they are doing is far beyond just the job itself with a greater commitment and the impact it has." – Ernesto Tusa, Research Portfolio Manager



Geneva is honored to advance METRC's mission to identify and prioritize the most critical issues challenging recovery from severe extremity trauma through exceptional program management, innovative scientific research, and regulatory guidance. Geneva partners with METRC to advance research in the following ways:

1. Navigate regulatory affairs and DHA policy changes

Geneva interprets guidance from the Defense Health Agency (DHA) and navigates policy changes to remain in federal compliance. With almost three decades of experience working with the DoD, Geneva reviews and interprets government policies, manages cooperative research and development agreements (CRADA), statements of work (SOW) and translates DoD language on behalf of Johns Hopkins University.

2. Remove the pre-award burden from the principal investigator

Geneva's commitment to fulfilling the sponsor's objectives removes the administrative burden of proposal preparation while upholding high ethical standards so that investigators can focus on technical or scientific components of their proposals, thereby increasing the chances of success. Geneva's METRC portfolio team provides comprehensive, friendly, and professional proposal development and support services while exhibiting leadership in research administration.

RESEARCH COLLABORATIONS

METRC's success is a testament to the power of civilian and military trauma center collaborations on critical research issues, leveraging the strength that comes from engaging patients and providers from across multiple centers.

These research programs rely on a multi-disciplinary approach that combines the clinical insights of the military and civilian orthopaedic surgeons and rehabilitation specialists, the research acumen of a world-renowned clinical research center, and the high volumes of patients with severe injuries that are treated at major Level I trauma centers and MTFs across the nation.

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 rehabilitative medical research adds value to collaborators when responding to requests for proposals.

3. Implemented the use of a single IRB for multi-center studies to streamline and optimize study execution

Institutional Review Boards (IRBs) play a critical role in reviewing and approving studies involving human research participants. Studies are increasingly conducted at multiple sites to help increase the number and diversity of the participants, improve operational efficiencies, and accelerate the generation of research results. However, for most multi-site studies, the IRB at each participating site conducts an independent review, adding time to research timelines. To address this bottleneck, Geneva helped multi-site studies conducting the same protocol for METRC use a single IRB to carry out the ethical review of the proposed research.

To date, more than 70 clinical centers throughout the U.S. and Canada have enrolled at least one participant into a METRC Study with the top enrolling centers contributing more than 1,000 study participants each.

4. Recruit and retain highly skilled and qualified personnel

METRC has multiple research projects in Geneva's portfolio and there is value in having longevity in personnel at those projects. It can be difficult to staff a person at 20% but because Geneva has more than 300 research programs, Geneva has been successful at finding and retaining top talent on METRC project by sharing personnel across multiple studies.

The Geneva network includes 400+ current employees dedicated to the mission. Geneva's screening and qualification process, competitive benefits packages, and team-oriented spirit results in a high rate of incumbent capture and a low turnover rate.

5. Share real-time study data using RED Cap

The REDCap data management functionality allows for a web-based distributed data entry system using most web browsers to access an internet-connected database server. The system permits the METRC Coordinating Center and participating clinical sites to have access to data in real time.



IMPACT ON MILITARY MEDICINE



STUDY AREAS

- Early acute management
- Prevention and treatment of acute and chronic infection
- Reconstructive surgery and non-surgical management to improve healing
- Prediction and prevention of secondary conditions and long term health effects
- Management of pain and psychosocial sequelae
- Rehabilitation intervention
- Optimization of prosthetic and orthotic function
- Outcomes measurement and translation



Extremity trauma is common in the military and civilian settings. Two-thirds of injuries treated at trauma centers in the U.S. involve one or more extremity injuries. METRC has been successful in maintaining the engagement of several leading, high volume, level I trauma centers that form the core of METRC and together, they manage 15,432 major fractures annually.

Geneva has participated in 17 study protocols including:

- **Alter-G:** RCT to examine the effectiveness of advanced early weight bearing progression using the Alter-G anti-gravity treadmill compared to standard of care physical therapy.
- **BIOBURDEN:** The assessment of severe extremity wound bioburden at the time of definitive wound closure or coverage, and correlation with subsequent post-closure deep wound infection.
- **NERVE:** Observational outcome study of peripheral nerve repair and reconstruction.
- **OXYGEN:** RCT to assess the efficacy of supplemental perioperative oxygen in the prevention of surgical site infections
- **PREVENT CLOT:** A randomized pragmatic trial comparing the non-inferiority of aspirin versus low molecular weight

heparin in prevention of death due to pulmonary embolism and others or venous thromboembolism.

- **PRIORITI-MTF:** A before-after prospective study to assess long-term benefits of the Intrepid Dynamic Exoskeletal Orthosis combined with a physical therapy program, the Return to Run Clinical Pathway.
- **pTOG:** RCT comparing rhBMP-2 vs. autograft for critical size tibial defects.
- **REPAIR:** RCT to compare efficacy of usual care physical therapy with usual care physical therapy combined with blood flow restricted training.
- **TAOS:** RCT comparing outcomes for patients undergoing a transtibial amputation and receiving an end-bearing tibia-fibula synostosis vs. standard posterior flap procedure.
- **VANCO:** RCT to compare efficacy of using local vancomycin powder in the prevention of surgical site infections.
- **Weight Bearing:** To compare outcomes following early vs. delayed weight bearing for adult patients treated operatively for an ankle fracture without syndesmodic fixation. Pilot study will be conducted with patients with unicondylar plateau fractures.

COLLABORATE WITH GENEVA

Geneva is proud to have almost 30 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 lead the study protocols
The Departments of Clinical Investigations who provide regulatory support
The hospital staff, departments, and Command leadership who support the research
The human participants who selflessly enroll in clinical trials
Geneva personnel that lead the conduct of the research

*We are grateful to everyone who makes this research possible. Thank you for your
commitment, dedication and unwavering support.*



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