

Joint Warfighter Medical Research Program

Strategic Plan

INTRODUCTION

The Congressionally Directed Medical Research Programs represents a unique partnership among Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas. Programs managed by the CDMRP have formalized strategic plans that identify program-specific research priorities; how to best address these urgencies; short- and long-term goals; investment strategies; and ways to recognize and evaluate program successes with respect to program priorities.

The CDMRP's Joint Warfighter Medical Research Program Strategic Plan identifies strategic priorities, outlines overarching research goals, and provides a framework to achieve those goals that is adaptable to changes in the medical research environment. The JWMRP Strategic Plan is reviewed and updated annually during the Vision Setting meeting.



JWMRP BACKGROUND AND OVERVIEW

The JWMRP is unique among the CDMRP's Congressional Special Interest programs in that it is focused on the continuity of ongoing medical research and development projects that are relevant to the Warfighter. In fiscal year 2012, Congress directed the JWMRP to support the logical continuation of successful projects previously funded with DOD CSI funding. Congress expanded the program in FY18 to additionally fund the continuation of projects previously supported with DOD core funds, which are part of the annual DOD budget set by Congress and the president, known as the President's Budget. This expansion allows the program to also support important non-CSI efforts that may otherwise have funding shortfalls.

The program augments and accelerates projects that address high-priority DOD and Service-specific medical requirements and close capability gaps. JWMRP does not support new projects or basic research. Candidate projects should be sufficiently advanced and demonstrate a clear benefit to military medicine. Congress has previously appropriated JWMRP funding on an annual basis and there is no guarantee of future funding.

The JWMRP currently funds late-stage science and technology, or S&T, projects which are focused on technology development, including applied and translational research, as well as advanced development projects which include the delivery and fielding of medical capabilities by the Services' project management offices. Having this S&T and advanced development funding balance helps to bridge the gap that often exists between basic science and successful military medical solutions.

VISION: Expedited delivery of highly impactful and effective military medical solutions

MISSION: Support the logical continuation of DOD-funded research and development projects that augment and accelerate high-priority medical requirements to meet the needs of Service members and other Military Health System beneficiaries

FUNDING HISTORY

Congressional appropriations for the JWMRP total \$595 million from FY12-FY23. CDMRP made a total of 282 JWMRP awards, funding 182 individual projects from FY12- FY22. Current JWMRP projects align to a diverse set of DOD medical research priorities, including military infectious diseases, military operational medicine, and combat casualty care. By focusing on early and advanced technology development and establishing the highest priorities each year, the JWMRP provides a pathway to accelerate transition of military medical products to military health care providers in support of the Warfighter.

RESEARCH AND FUNDING ENVIRONMENT

The JWMRP has impacted the landscape of military medical research by accelerating the continuation of important DOD-funded efforts to develop military medical solutions spanning a range of DOD medical research areas and studies.

To be eligible for JWMRP continuation support, projects must be previously supported with DOD CSI or DOD core funding. The research funding landscape relevant to the program is quite broad. In the current environment, DOD CSI-funded projects are largely supported by the CDMRP, with numerous CDMRP programs aligning with the vision, mission, and congressional language of the JWMRP. Most extramural DOD core-funded projects are supported by the United States Army Medical Research and Development Command through the Defense Medical Research and Development Program. Projects carried out at any intramural DOD laboratories supported with Army, Navy, Air Force, or U.S. Special Operations Command funding or with Defense Health Program Research, Development, Test, and Evaluation funding are also considered to be core-funded projects. In addition, the JWMRP can support the continuation of DOD Small Business Innovation Research/Small Business Technology Transfer projects that have completed Phase II.

The JWMRP holds an annual Vision Setting meeting where a Programmatic Panel, representing science and technology and advanced development across various DOD medical research areas, assesses the state of the science and any emerging needs. These subject matter experts review and prioritize medical research and development gaps and unfinanced medical requirements or funding shortfalls by research area. They also ensure that the JWMRP is soliciting for and funding research that is complementary and non-overlapping with other DOD core efforts.

RESEARCH PORTFOLIO

From FY18-FY22, the JWMRP has invested approximately 70% of its budget in S&T research and 30% in advanced development, as shown in **Figure 1**. This FY18-FY22 investment supported 43 individual S&T projects and 27 advanced development projects.



Figure 1: FY18-FY22 Investment by Budget Activity

The FY18-FY22 portfolio reflects investment in medical research areas in both the S&T and advanced development domains, as shown in **Figure 2**. With some research areas sunsetting over the years, investments in projects related to medial simulation and information sciences, radiation health effects, and clinical and rehabilitative medicine have decreased. Projects that align with combat casualty care, military operational medicine, and military infectious diseases now comprise the largest portion of the portfolio.



Figure 2: FY18-FY22 Investment by DOD Medical Research Area

Figure 3 shows that the majority of research investments in the FY18-FY22 JWMRP portfolio are focused on Devices and Clinical and Experimental Therapeutics. Approximately one-third of JWMRP awards support clinical studies or clinical trials in various stages.



Figure 3: FY18-FY22 Investment by Research Type

Figure 4 shows that 70% of the projects in the FY18-FY22 portfolio are in the technology readiness level range of 5 - 8 (TRL 5 to TRL 8), which demonstrates that the program is being executed as intended with a focus on pushing Warfighter-relevant products through the acquisition life cycle. Currently, just over 80% of JWMRP awards have projected outcomes that are focused on technology development, with the remainder in knowledge product development.



Figure 4: FY18-FY22 Projects by Technology Readiness Level

Across the program, approximately two-thirds of JWMRP awards are executed as research and development contracts, versus assistance agreements, which aligns with the program's support of product development efforts with clear deliverables and/or prototypes, as well as the augmentation of existing advanced development contracts. About one-third of JWMRP awards involve DOD intramural performers, which demonstrates the support for highly military-relevant efforts carried out by DOD laboratories and military treatment facilities.

NOTABLE ADVANCES SUPPORTED BY JWMRP FUNDING

- **DSUVIA® sufentanil sublingual tablet**¹: JWMRP accelerated development of the oral formulation of this drug for battlefield pain management by 18-24 months by enabling parallel task completion, faster FDA filing and approval in 2018, and awarding of a Federal Supply Schedule contract.
- Sprint® peripheral nerve stimulation system²: JWMRP advanced development of this device as a non-opioid treatment for post-amputation residual and phantom limb pain, moving it along the pathway to 510(k) FDA clearance in 2018, with other broader indications approved in 2021 and 2023.
- SonicEye® wearable ultrasound probe³: JWMRP advanced development of this device for battlefield use by supporting transition from a laptop display to a wireless ultrawide-band smart phone display, with 510(k) FDA clearance of the complete portable system achieved in 2020.
- APRU6L portable autonomous blood refrigeration unit⁴: JWMRP augmented an Air Force SBIR effort to transition this device to the battlefield to bring more fresh whole blood to field-forward settings to improve survivability.

STRATEGIC DIRECTION

The JWMRP's strategic guidance is largely directed by language in the Defense Appropriations Act.

JWMRP Congressional Language: Funds shall be used to augment and accelerate high priority Department of Defense and Service medical requirements and to continue both core and Congressionally-directed prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. These funds shall not be used for new projects or basic research, and they shall be awarded at the discretion of the Secretary of Defense following a review of medical research and development gaps, as well as unfinanced medical requirements of the Services.⁵

With constantly changing DOD medical requirements and capability gaps, it is critical for the program to coordinate with Programmatic Panel members from the Defense Health Agency (DHA), Army, Navy, and Air Force, at the S&T and advanced development levels, to identify joint and Service-specific priority areas each year. S&T priority areas are focused on research that will feed the pipeline to advanced development. The panel members also provide feedback on advanced development projects nominated for JWMRP funding following a prior review of unfinanced medical requirements of the Services and high-priority projects with funding shortfalls. This

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important input ensures that the JWMRP has a unified vision and focus on supporting projects that are relevant to the highest priorities for research and development and for advanced product development.

STRATEGIC PRIORITIES

Historically, JWMRP funding has supported late-stage technology development, demonstration, and maturation and has included both clinical research and clinical trials. Beginning in FY23, projects submitted for JWMRP funding must be considered TRL 5 or greater, meaning that efforts have already advanced from technology development to technology demonstration. The projects funded through the JWMRP appropriation are expected to benefit both military and civilian communities, with particular focus on projects that impact our forward deployed Forces and rehabilitation efforts for injured military.

Near-Term Priorities/Focus Areas

At the FY23 JWMRP Vision Setting, the Program identified our gap-driven near-term priority areas, which all align with Defense Health Program medical Research, Development, Test, and Evaluation priorities.

- *Endemic and Emerging Disease Threat* priorities are focused on preventative and therapeutic measures for endemic and emerging infectious diseases (malaria and COVID excluded) and for combat-associated wound infections in austere, prolonged field care, and large-scale combat environments. Measures in the late preclinical or early clinical stage of development, preferentially with initial preclinical efficacy and toxicity studies completed, are targeted.
- **Operational Medicine and Readiness** priorities center on injury prevention, rapid return-to-duty capabilities, and rehabilitation solutions; strategies and technologies that address sensory system function impacted by combat-related injury; and portable neuromodulation devices to treat behavioral health conditions and alleviate comorbid symptoms.
- *Environmental Medicine* priorities are focused on extreme cold conditions, including countermeasures to prevent injury and illness, enhance performance of Service Members, and provide solutions to enhance the provision of combat casualty care in this weather environment.
- *Combat Casualty Care* priorities include novel solutions for hemorrhage control and resuscitation, combat wound solutions, intelligent diagnostic imaging technologies, autonomous care and evacuation capabilities, and prophylactic medical countermeasures for nuclear injury.

Medium- to Long-Term Priorities

Pending new Congressional guidance, future JWMRP funding priorities will continue to align with select Defense Health Agency S&T portfolio areas⁶ and will address targeted capability gaps to further increase the impact of JWMRP funding, feeding the research pipeline to advanced development. To facilitate this coordination, DHA portfolio leads will be integrated into the JWMRP Programmatic Panel alongside Service and USSOCOM representatives. S&T priorities are expected to be adapted on an annual basis following a review of medical research and development gaps at Vision Setting. Similarly, advanced development priorities are expected to change annually following a review of unfinanced medical requirements and funding shortfalls. Medium- to long-term priorities include the following:

- Support research that aligns with identified S&T and advanced development priorities identified by the Services and provides balance within and across the Services' medical research portfolios
- Support research that augments and/or accelerates clinical, technical, or materiel/knowledge product development efforts that directly benefit military medicine
- Support research and development of military medical products or outcomes that have transition potential
- Support research that is relevant and impactful to Service Members and other Military Health System beneficiaries

INVESTMENT STRATEGY

The JWMRP aims to push projects through the product development process and bridge the gap between basic research and delivery of viable military medical solutions. The JWMRP will use the award vehicle that is most appropriate for a particular development effort, whether it be a grant, cooperative agreement, contract, other transaction authority award, or modification to an existing award.

To solicit S&T projects, the JWMRP offers a Broad Agency Announcement called the Military Medical Research and Development Award. The BAA mechanism streamlines the process for awarding contracts and allows for OTA awards if appropriate for a particular project. The MMRDA does not support basic research, and proposed efforts must be a logical continuation of projects that previously received DOD CSI or DOD core funding. A MMRDA Clinical Research/Trial Option specifically supports clinical research/observational studies, all phases of clinical trials/interventional studies, and correlative studies in support of the

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development of promising pharmaceutical or biologic candidates, medical devices, and technologies with a higher total cost limit than the standard MMRDA. All applications must address at least one of the Focus Areas detailed in the funding opportunity.

Based on feedback from the Director of the Office of the Under Secretary of Defense for Research and Engineering at the 2021 DHA JWMRP Review & Analysis, beginning in FY22 the JWMRP integrated a new project solicitation process into the DHP acquisition spend plan build to promote true product development augmentation and acceleration by supporting high-priority existing advanced development contracts. Per congressional language, the JWMRP Advanced Development Augmentation Funding process is focused on a review of unfinanced medical requirements/funding shortfalls that are discussed and prioritized by the Joint Acquisition Enterprise and the DHA Program Manager for Pharmaceuticals, Devices, and Medical Support Systems. Nominated projects must meet certain criteria to be eligible for JWMRP funding:

- Funding must accelerate a DHP-funded acquisition program,
- Project must have an existing contract, or OTA, in place at the time of nomination,
- Effort must be within the scope of the existing contract,
- Existing project should be at TRL 5 or above,
- Funding requested must not put the contract over its funding ceiling.

Advanced development project nominations are discussed by the joint Programmatic Panel at Vision Setting and feedback is summarized before the funding recommendations are routed to the USAMRDC Commanding General for final approval.

With the ongoing transition of the CDMRP to the DHA, we anticipate increased coordination with the DHA to aid in adapting the JWMRP execution plan accordingly. That coordination has begun with DHA leaders at the S&T and advanced development levels.

MEASURING PROGRESS

The JWMRP measures near-term program success by assessing receipt and funding of high-quality submissions that contribute toward meeting the intent and strategic goals of the program. Award technical and research progress, including publications, patents, and other outcomes, as well as the development of technology and knowledge products, is tracked on a quarterly reporting basis.

In the medium to long term, the JWMRP measures program success by the advancement accomplished toward delivering products and outcomes that will benefit military medicine. To measure this advancement, the program monitors the success rates of achieving relevant regulatory milestones. These milestones include whether device development or drug/therapeutic and vaccine development projects are poised to file for FDA approval upon project completion; or whether enough data has been acquired to submit an Investigational Device Exemption or an Investigational New Drug application with the FDA at the end of the period of performance. For clinical studies that support knowledge product development and are therefore not under FDA regulation, the JWMRP tracks the publication of clinical practice guidelines.

Information regarding project status is provided to the JWMRP Programmatic Panel for their consideration in developing the annual program investment strategy.

REFERENCES

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