January 2025

CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Peer Reviewed Medical Research Program

Strategic Plan

INTRODUCTION

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

BACKGROUND AND OVERVIEW

Congress established the Peer Reviewed Medical Research Program in 1999 to fund military health-related research of exceptional scientific merit aimed at improving the health and well-being of Service Members and their Families, Veterans and the American public.

Recommendations from a programmatic panel of leading scientists, clinicians from the DOD, Office of the Assistant Secretary of Defense for Health Affairs, VA, Department of Health and Human Services and academia respond to congressional intent and inform the following mission and vision statements:

VISION: Improve the health, care and well-being of all military Service Members and their Families and Veterans

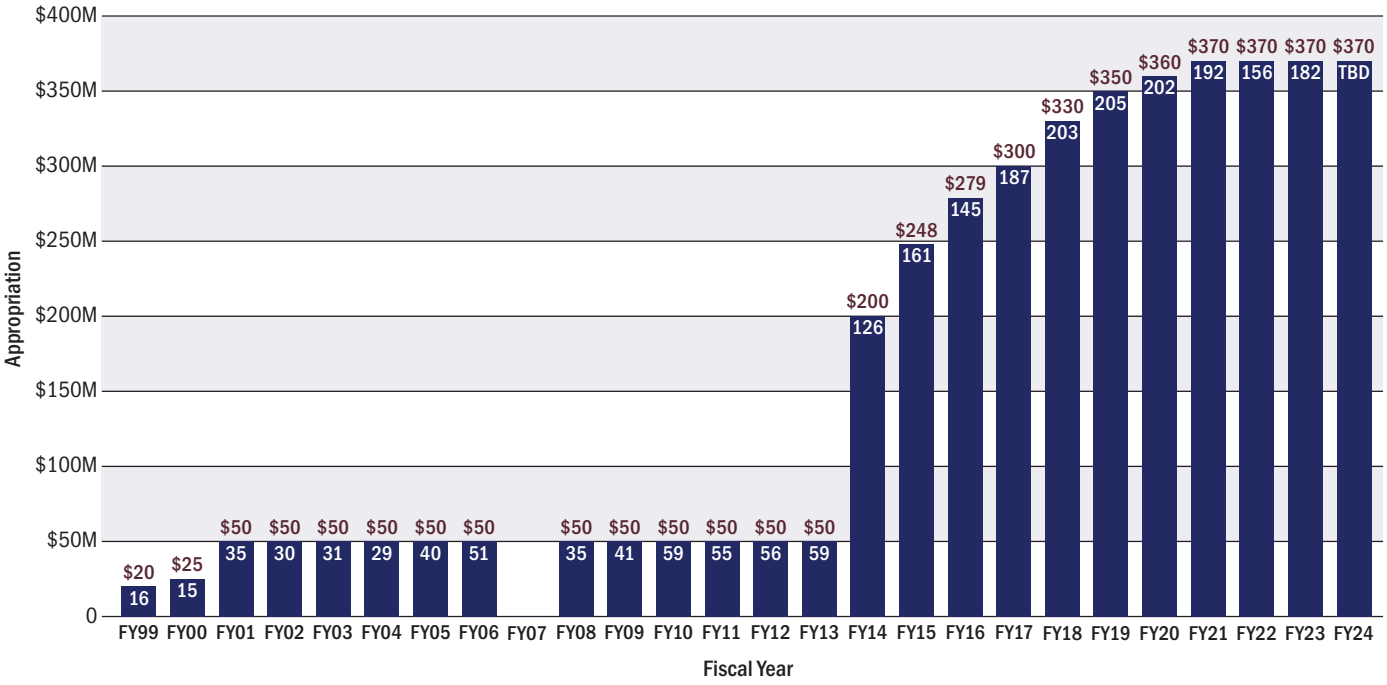
MISSION: Encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, their Families and Veterans

In 1993, the National Academy of Sciences Institute of Medicine recommended that CDMRP-managed programs use a two-tier review process for proposal evaluation. The first tier, scientific peer review, evaluates the scientific merit of an application against published review criteria. The second tier, a programmatic review led by a programmatic panel, compares applications to each other and makes funding recommendations based on scientific merit, relevance to military health, relative impact and portfolio composition. The two-tier review process ensures scientific excellence and programmatic relevance for all PRMRP funded awards in accordance with Congressional intent.

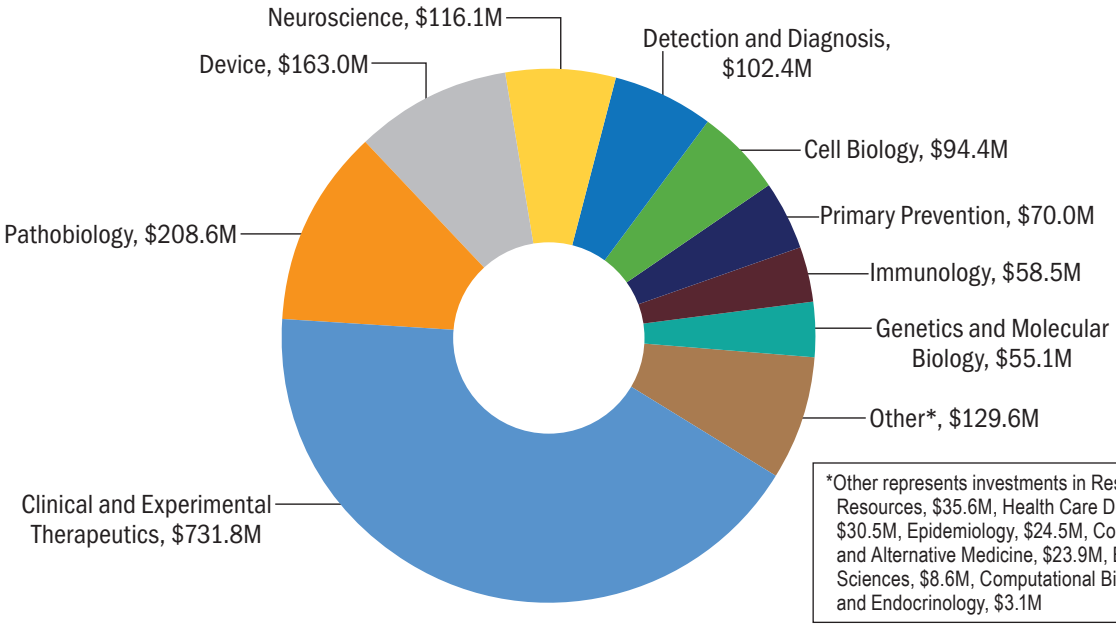
FUNDING HISTORY

Since PRMRP's inception in FY99, the program received a total of $4.19 billion in congressional appropriations. Congressional appropriations committees provide PRMRP with specific language in the Defense Appropriations Bill stipulating that the program is to support research of clear scientific merit and direct relevance to military health in specified topic areas. In FY14, the appropriation quadrupled to $200M and continued to increase steadily. The program annually solicits for applications and reviews submissions based on their scientific merit and alignment to the congressionally directed topic areas. Through FY23, the PRMRP funded 2,327 research awards in 192 unique diseases and conditions across 16 research categories, which resulted in 2,398 peer-reviewed publications and 571 patent applications/issues. Award data, abstracts and associated publications from funded research can be found on the *CDMRP website*.

PRMRP Funding History, FY99-FY24



PRMRP Investments by Research Category, FY19-FY23



*Other represents investments in Research Resources, $35.6M, Health Care Delivery, $30.5M, Epidemiology, $24.5M, Complementary and Alternative Medicine, $23.9M, Biobehavioral Sciences, $8.6M, Computational Biology, $3.4M, and Endocrinology, $3.1M

STRATEGIC DIRECTION

A hallmark of the PRMRP is the partnership among patients, survivors, or family members in addition to, scientists and clinicians from all branches of the military, VA, DOD Counterparts, Department of Health and Human Services, academia and advocacy organizations. With these relevant stakeholders represented on the PRMRP programmatic panel, the program develops its strategic direction based on the scope of problems affecting Service Members and their families, Veterans and the American public. The strategic plan emphasizes individuals with experience of the diseases and conditions directed by Congress. To make the most impact, PRMRP releases funding opportunities to address research and clinical gaps related to global health issues directly related to military health.

Resources for the PRMRP strategic plan include the following:

- Congressional Language for the PRMRP
  - Support research of “clear scientific merit” and “direct relevance to military health”
  - Research areas considered under PRMRP funding are restricted to the diseases and conditions specified in the congressional language*
- Senate Explanatory Statement for the DOD Appropriations Bill
- Joint Requirements Oversight Council Initial Capabilities Documents
- Defense Health Program Guidance for Research and Development Planning Activities
- Deputy Assistant Secretary of Defense, Health Readiness Policy and Oversight Initial Capabilities Documents
- Guidance from Stakeholders

INVESTMENT STRATEGY

At the beginning of every fiscal year, the PRMRP develops an investment strategy, based on the list of congressionally directed topic areas that supports research throughout the continuum of care, from early discovery through the development of ideas and products into clinical applications.

PORTFOLIO-DRIVEN APPROACH

The PRMRP implements a portfolio-driven approach by grouping related topic areas with strategic goals as a framework to address critical gaps in major research areas. The PRMRP’s portfolio-driven approach offers several advantages, including the opportunity to address prioritized needs and close gaps through targeted funding, present clear and simplified guidance to investigators and lend continuity in the investment strategy as specific topic areas directed by Congress may change from year to year. Awards under each congressionally directed topic area are managed within one of the PRMRP portfolios:

- Autoimmune Disorders and Immunology
- Cardiovascular Health
- Hemorrhage Control and Blood Products
- Infectious Diseases
- Internal Medicine
- Neuroscience
- Nutrition and Metabolism
- Orthopaedic Medicine
- Rare Diseases and Conditions
- Respiratory Health

STRATEGIC GOALS

In an effort to clearly define portfolio-specific strategic goals, the PRMRP holds roundtable discussions with advocacy organizations, representing diseases and conditions from the congressionally directed topic areas, to identify unmet needs and key research gaps. The outcomes of these discussions, in addition to feedback from the DOD, VA, HHS and other relevant stakeholders, informs the portfolio-specific strategic goals aligned to the continuum of care, i.e., foundational, prevention, diagnosis, treatment and epidemiology.

*This list may vary yearly.

PRMRP Investments by Portfolio and Congressionally Directed Topic Areas, FY19-FY23*

Autoimmune Diseases and Immunology — $95.3M (5.5%)

- Celiac Disease, $6.7M
- Eczema, $3.2M‡
- Food Allergies, $5.6M
- Guillain-Barre Syndrome, $5.0M
- Inflammatory Bowel Disease, $45.9M
- Rheumatoid Arthritis, $22.0M‡
- Scleroderma, $6.6M
- Sustained-Release Drug Delivery, $0.3M‡

Cardiovascular Health — $168.3M (9.7%)

- Cardiomyopathy, $61.7M‡
- Congenital Heart Disease, $45.5M
- Diabetes, $4.3M‡
- Familial Hypercholesterolemia, $5.4M‡
- Hypercholesterolemia, $0.3M‡
- Hypertension, $10.1M‡
- Nutrition Optimization, $0.2M‡
- Proteomics, $8.5M
- Vascular Malformations, $27.7M
- Women's Heart Disease, $4.6M‡

Hemorrhage Control and Blood Products — $104.6M (6.1%)

- Hemorrhage Control, $87.3M‡
- Pathogen-Inactivated Blood Products, $2.5M‡
- Trauma, $14.8M‡

Nutrition and Metabolism — $94.2M (5.5%)

- Diabetes, $68.2M‡
- Nutrition Optimization, $22.2M‡
- Sustained-Release Drug Delivery, $3.8M‡

Infectious Diseases — $150.8M (8.7%)

- Antimicrobial Resistance, $12.3M‡
- Emerging Infectious Diseases, $17.8M‡
- Emerging Viral Diseases, $24.0M‡
- Hepatitis B, $22.8M
- Malaria, $33.4M
- Neuroinflammatory Responses to Emerging Viral Diseases, $0.3M‡
- Plant-Based Vaccines, $18.0M‡
- Sustained-Release Drug Delivery, $0.3M‡
- Tuberculosis, $16.1M‡
- Viral Diseases, $5.8M‡

Internal Medicine — $171.0M (9.9%)

- Endometriosis, $5.9M‡
- Focal Segmental Glomerulosclerosis, $48.0M
- Interstitial Cystitis, $4.4M
- Lymphatic Disease, $6.3M‡
- Lymphedema, $0.6M
- Nephrotic Syndrome, $6.3M
- Pancreatitis, $36.5M
- Polycystic Kidney Disease, $47.5M
- Pressure Ulcers, $15.5M‡

Neuroscience — $265.2M (15.3%)

- Chronic Migraine And Post-Traumatic Headache, $26.9M‡
- Eating Disorders, $9.3M
- Maternal Mental Health, $10.3M
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, $3.3M
- Neuroinflammatory Responses to Emerging Viral Diseases, $17.3M‡
- Non-Opioid Therapy for Pain Management, $45.2M‡
- Peripheral Neuropathy, $19.2M
- Sleep Disorders, $5.3M‡
- Sleep Disorders and Restriction, $44.9M‡
- Suicide Prevention, $29.0M
- Sustained-Release Drug Delivery, $8.8M‡
- Trauma, $45.7M‡

Orthopaedic Medicine — $111.1M (6.4%)

- Arthritis, $23.5M‡
- Musculoskeletal Disorders, $13.4M‡
- Musculoskeletal Disorders (related to acute and chronic bone conditions and injuries), $14.6M
- Musculoskeletal Health, $24.1M‡
- Orthopaedics, $3.8M‡
- Post-Traumatic Osteoarthritis, $9.0M‡
- Sustained-Release Drug Delivery, $14.8M‡
- Trauma, $7.9M‡

Rare Diseases and Conditions — $239.4M (13.8%)

- Dystonia, $13.0M
- Ehlers-Danlos Syndrome, $0.3M
- Epidermolysis Bullosa, $24.8M
- Fibrous Dysplasia, $3.3M‡
- Fragile X, $15.1M
- Fragile X Syndrome, $1.8M‡
- Friedreich's Ataxia, $9.2M‡
- Frontotemporal Degeneration, $30.7M
- Hereditary Ataxia, $10.4M
- Hydrocephalus, $35.1M
- Mitochondrial Disease, $56.9M
- Myotonic Dystrophy, $20.0M
- Rett Syndrome, $15.3M
- Sickle-Cell Disease, $3.3M
- Von Hippel-Lindau Syndrome Benign Manifestations, $0.2M‡

Respiratory Health — $329.6M (19.1%)

- Acute Lung Injury, $23.3M‡
- Burn Pit Exposure, $9.5M‡
- Emerging Infectious Diseases, $3.4M‡
- Emerging Viral Diseases, $36.2M‡
- Lung Injury, $0.6M‡
- Pulmonary Fibrosis, $42.3M
- Respiratory Health, $188.5M
- Sustained-Release Drug Delivery, $8.8M‡
- Trauma, $11.7M‡
- Viral Diseases, $5.3M‡

** New topics in FY24: Accelerated Aging Processes Associated with the Military, Computational Biology for Precision Health, Congenital Cytomegalovirus and Far-UVC Germicidal Light*

‡ Topic areas not directed by Congress in FY24

PRMRP Portfolio Investments Across the Continuum of Care, FY19-FY23

	Foundational Studies	Prevention	Diagnosis	Treatment	Epidemiology	Total Awards	Total Investment
Autoimmune Diseases and Immunology	20		4	35	1	60	$95M
Cardiovascular Health	39	8	12	27	1	87	$168M
Hemorrhage Control and Blood Products	4		2	35	1	42	$105M
Infectious Diseases	10	30	8	40		88	$151M
Internal Medicine	41		6	52	3	102	$171M
Neuroscience	31	8	11	65	2	117	$265M
Nutrition and Metabolism	25	1	5	38		69	$94M
Orthopaedic Medicine	22	5	5	32	3	67	$111M
Rare Diseases	56		16	58	3	133	$239M
Respiratory Health	34	12	18	83	9	156	$330M
Total Awards	282	64	87	465	23	921	
Total Investment	$312M	$152M	$165M	$1,069M	$32M		$1.729B

The PRMRP strives to invest across all portfolios and the entire continuum of care. Between FY19-FY23, PRMRP funded research in each continuum of care category.

PRMRP FUNDING PIPELINE

The PRMRP is committed to funding research with the potential to profoundly impact the development and implementation of medical devices, drugs and clinical guidance across the research pipeline, from basic discovery and mature concept to translational research and clinical trials. Annually, the PRMRP solicits research applications through one of the funding opportunity announcements, outlined in the table below, that must address both a topic area and a portfolio-specific strategic goal. The announcements include the program's strategic goals to help investigators understand the research priorities and unmet needs for each disease and condition. The PRMRP offers funding opportunities that can support research within the entire spectrum of the development pipeline. All funding opportunities are available to all PRMRP portfolios and all congressionally directed topic areas. The PRMRP supports and executes congressional intent through funding opportunities, which are broadly applicable to all congressionally directed topic areas. The addition of strategic goals helps to direct researchers to unmet needs identified by the program.

FY24 PRMRP PORTFOLIOS	Basic Research	Translational Research	Clinical Trials/Clinical Research
AUTOIMMUNE DISORDER AND IMMUNOLOGY CARDIOVASCULAR HEALTH INFECTIOUS DISEASES INTERNAL MEDICINE NEUROSCIENCE ORTHOPAEDIC MEDICINE RARE DISEASES AND CONDITIONS RESPIRATORY HEALTH	**Discovery Award** • Novel/breakthrough exploratory research, high-risk/high-reward **Investigator-Initiated Research Award** • Preclinical expansion, replication and/or comparative studies to validate preliminary or published data	**Impact Award** • Mature research studies with potential near-term clinical impact for patients **Technology/Therapeutic Development Award** • Final steps of clinical translation • IND-/IDE- enabling studies or studies required to transition a product of prototype utility	**Clinical Trial Award** • Early-phase or large-scale interventional clinical trials to measure safety, effectiveness and/or efficacy outcomes **Lifestyle and Behavioral Health Interventions Research Award** • Clinical trials/research focused on non-pharmacological therapies, non-invasive devices, patient outcomes, or quality of life

PRMRP Portfolio Investments Across the Research Pipeline, FY19-FY23

	Discovery Research	Mature Research	Translational Research	Clinical Research	Total Awards	Total Investment
Autoimmune Diseases and Immunology	21	25	12	2	60	$95M
Cardiovascular Health	34	35	13	5	87	$168M
Hemorrhage Control and Blood Products	9	17	14	2	42	$105M
Infectious Diseases	38	33	11	6	88	$151M
Internal Medicine	37	49	9	7	102	$171M
Neuroscience	38	47	12	20	117	$265M
Nutrition and Metabolism	29	32	5	3	69	$94M
Orthopaedic Medicine	26	30	6	5	67	$111M
Rare Diseases	55	61	15	2	133	$239M
Respiratory Health	61	55	29	11	156	$330M
Total Awards	348	384	126	63	921	
Total Investment	$110M	$770M	$469M	$380M		$1.729B

The PRMRP strives to invest across the research pipeline for all portfolios. Between FY19-FY23, the PRMRP funded research in all stages of product development across all portfolios.

MEASURING PROGRESS

The PRMRP will measure near-term outcomes by tracking the amount of funding invested in each topic area, strategic goal and portfolio. The program will identify understudied topic areas and encourage research in those areas. In addition, the PRMRP will track publications, patents and clinical trials of funded research and expects these outcomes to vary based on the stage of the research projects. Frequent communication between the program staff and research investigators allows for monitoring award progress and execution.

Regarding medium- to long-term program success, in FY22 the PRMRP began an initiative to track historical investments and determine the contributions of PRMRP-funded projects toward successful product development from concept through commercialization. The program reviewed 1,063 closed awards to identify the approved use of drugs/devices/tools, funding sources, and funding levels throughout the developmental pipeline. Numerous outcomes were identified that highlight the impact of PRMRP support in the development of commercialized products to prevent/diagnose/treat diseases and conditions of special interest to the US Congress.

PRMRP Outcomes FY99-FY23

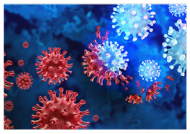
** Products are defined as drugs, devices, or tools; new technologies including software, decision support systems, or AI; clinical guidance that is implemented into standard medical practice and improves patient treatment; or freely available research tools.*

PRMRP-Supported Products

I-STAT® TEST FOR TRAUMATIC BRAIN INJURY

FDA-approved blood-based biomarkers to rapidly predict brain injury

LIAT™ ANALYZER



FDA-approved point-of-care device for diagnosis of viral infections

SPRINT® PNS SYSTEM

FDA-approved non-opioid therapy to treat lower back pain from overuse injuries

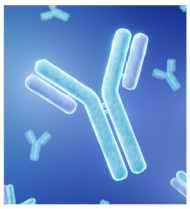
MeMED VB® AND MeMED KEY®

FDA-approved rapid diagnostic technology to distinguish between bacterial and viral infections in blood samples

NextSteps

A publicly available trauma survivors network for group support

NAXITAMAB



FDA-approved monoclonal antibody targeting the ganglioside GD2 for the treatment of high-risk neuroblastoma in the bone or bone marrow

VAZALORE™

An FDA-approved aspirin-lipid formulation for pain relief while minimizing damage to the stomach

M2-DEFICIENT SINGLE- REPLICATION VACCINE

An influenza vaccine with efficacy against drifted strains to provide universal flu immunogenicity

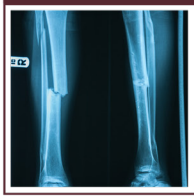
Low-Force Expanding-Adaptable Pediatric, LEAP™, Valve

A pediatric cardiac valve to treat congenital heart disease that expands to "grow" with the child

SHARC CATHETER

Self-Sensing Hemorrhage Control and Resuscitative Catheter to enable precise blood flow

OSTEO ADAPT BVF



A synthetic bone graft coated with a bone- inducing growth factor to mend open tibial fractures, Breakthrough Device Designation from the FDA

These PRMRP-supported products are examples of the work PRMRP supports across the congressionally directed topic areas.