TICK-BORNE DISEASE RESEARCH PROGRAM

CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

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VISION

To prevent the occurrence, better diagnose, and resolve or minimize the impact of Lyme disease and other tick-borne illnesses and conditions, with emphasis on burden of disease

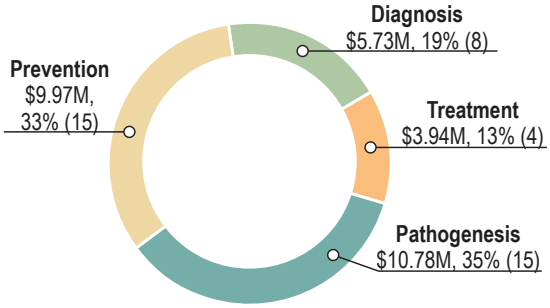
MISSION

To understand the pathogenesis of Lyme disease and other tick-borne illnesses and conditions, to deliver innovative solutions to prevent, diagnose, and treat their manifestations for the benefit of U.S. Service Members and the American public, and to disseminate this knowledge

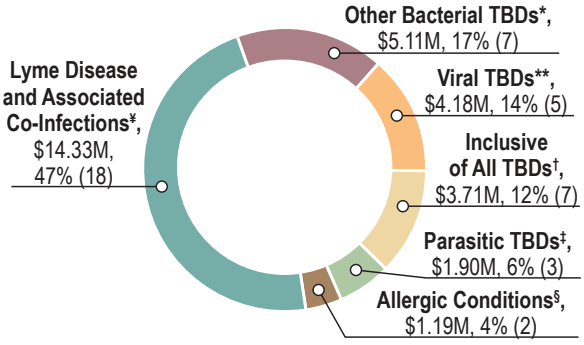
PROGRAM HISTORY

The Tick-Borne Disease Research Program (TBDRP) was established in FY16 due to the efforts of Lyme disease advocates. The TBDRP has received a total of $34M in congressional appropriations from FY16-FY21 and aims to support research to improve capabilities in tick-borne disease (TBD) prevention, diagnosis, and treatment.

As tick populations increase and expand geographically, new tick-borne pathogens and associated diseases/conditions continue to emerge.[1] Unfortunately, TBDs often go undiagnosed, or misdiagnosed, which can interfere with administering appropriate treatment. The study of TBDs is complicated by the breadth of conditions that result from infection with various bacterial, viral, and parasitic pathogens, and because a single tick bite can transmit more than one pathogen at a time. TBDs and conditions can negatively impact multiple body systems and have long-term health implications. To improve TBD diagnosis and subsequent treatment for civilian and military populations, more sensitive and accurate diagnostic tests are needed, as well as better understanding of the mechanisms behind these various infections and long-term effects on health. The TBDRP strives to address these fundamental knowledge gaps in the field of TBDs.



TBDRP Portfolio By Research Focus FY16-FY21 (42 Awards)



TBDRP Portfolio by Disease/ Condition FY16-FY21 (42 Awards)

¥ "Lyme disease and associated co-infections" refers to studies of Lyme disease alone or with various co-infections commonly diagnosed with Lyme disease. 50% of these awards directly investigate or have implications in Post-Treatment Lyme Disease Syndrome (PTLDS), or persistent/chronic symptoms of Lyme disease.
* Currently includes Rickettsiosis and Ehrlichiosis
** Currently includes Powassan, Crimean-Congo Hemorrhagic Fever, and Tick-Borne Encephalitis viruses
† Indicative of studies involving approaches applicable to any/all TBDs
‡ Currently refers to Babesiosis
§ Currently refers to Alpha-Gal Syndrome

[1] https://www.cdc.gov/media/dpk/diseases-and-conditions/lyme-disease/index.html.

2021 Congressional Appropriations, Research Investment, and Withholds and Management Costs

Congressional Appropriations	*Research Investment*	*Withholds and Management Costs*
$7M	Career Development Award.....$908,763 Idea Development Award ..... $5,302,613 Modification to ongoing awards $15,000	USAMRDC .....$135,320 SBIR/STTR ..... $234,000 Mgt Costs (6.1%)..... $404,304
Total: $7M	**Total:** $6,226,376	**Total:** $773,624

MILITARY RELEVANCE

- Approximately 6,000 active-duty Service Members and nearly 56,000 Service Member beneficiaries were diagnosed with a reportable TBD between 2006–2020.[1]
- Lyme disease accounted for ~80% of TBDs diagnosed in Service Members and their beneficiaries between 2006–2020.[1]
- Lyme disease accounted for ~44% of all reportable medical event cases of vector-borne diseases (VBD) (confirmed, probable, and suspected), and Lyme was the most common of the VBDs reported from 2016–2020.[2]

RESEARCH HIGHLIGHTS

Development of a Bactericidal, Long-Half-Life, OspA-Specific Human Monoclonal Antibody as a Novel Pre-Exposure Prophylaxis (PrEP) for Lyme Disease

Dr. Yang Wang, University of Massachusetts Medical School

Current Lyme disease prevention strategies rely heavily on physical barriers and the use of tick repellents, which require compliance and reapplication. Service Members' primary line of defense from tick bites is the use of permethrin-treated uniforms, which become less effective as potency wanes with washing. With funding from a TBDRP Investigator-Initiated Research Award, Dr. Yang Wang and her team of experts from MassBiologics are developing a pre-exposure immunoprophylaxis, or PrEP, for Lyme disease prevention. With the use of human monoclonal antibodies, the PrEP offers a longer window of protection from infection by Lyme disease-causing bacteria versus traditional vaccines. A single dose of human antibody PrEP could act as an additional barrier of protection from Lyme disease, benefiting Service Members, their beneficiaries, and the American people. Results from this TBDRP-funded effort helped to advance PrEP along the pathway to FDA approval, with an Investigational New Drug application approved this year and a phase 1 clinical trial now underway for the lead candidate.

TBDRP Research Portfolio by Focus Area

Understanding the pathogenesis of TBDs at the cellular and molecular level

- Studies to elucidate the mechanisms and immune responses associated with Lyme disease, post-treatment Lyme disease syndrome, Babesiosis, Rickettsiosis, and tick bite-induced red meat allergy
- Studies to assess the impact of tick-borne disease co-infections

Developing effective and widely acceptable measures for the prevention of TBDs

- Adaptive barrier controlled release device for the prevention of Service Member tick bites
- PrEP for Lyme disease
- Vaccine candidates to protect against Ehrlichiosis, Rickettsiosis, Powassan virus, and Lyme disease

Elucidating new and effective TBD treatments

- Pre-clinical studies of optimal drug combinations to eradicate Borrelia persisters for more effective treatment of persistent Lyme disease
- High-throughput screening to identify chemical inhibitors of Crimean Congo Hemorrhagic Fever

Improving detection and diagnosis of TBDs

- Lateral flow diagnostic assay for Rickettsia
- Pathogen-host molecular biosignature Lyme disease diagnostic assay
- Host-based and pathogen-based proteomic biosignatures for the diagnosis of Lyme disease in children

Wendy Adams, Bay Area Lyme Foundation, Programmatic Panel Member FY20-FY22

"I really appreciate the opportunity to serve on CDMRP because of its focus on innovation and impact for patients. High-risk, high-reward research is crucial to fund, because we need vastly improved diagnostics and treatments for both Lyme and other tick-borne diseases."

[1] Data from the Armed Forces Health Surveillance Branch (AFHSB); [2] AFHSB Feb 2021 Medical Surveillance Monthly Report

For more information, visit: **https://cdmrp.health.mil/tbdrp**