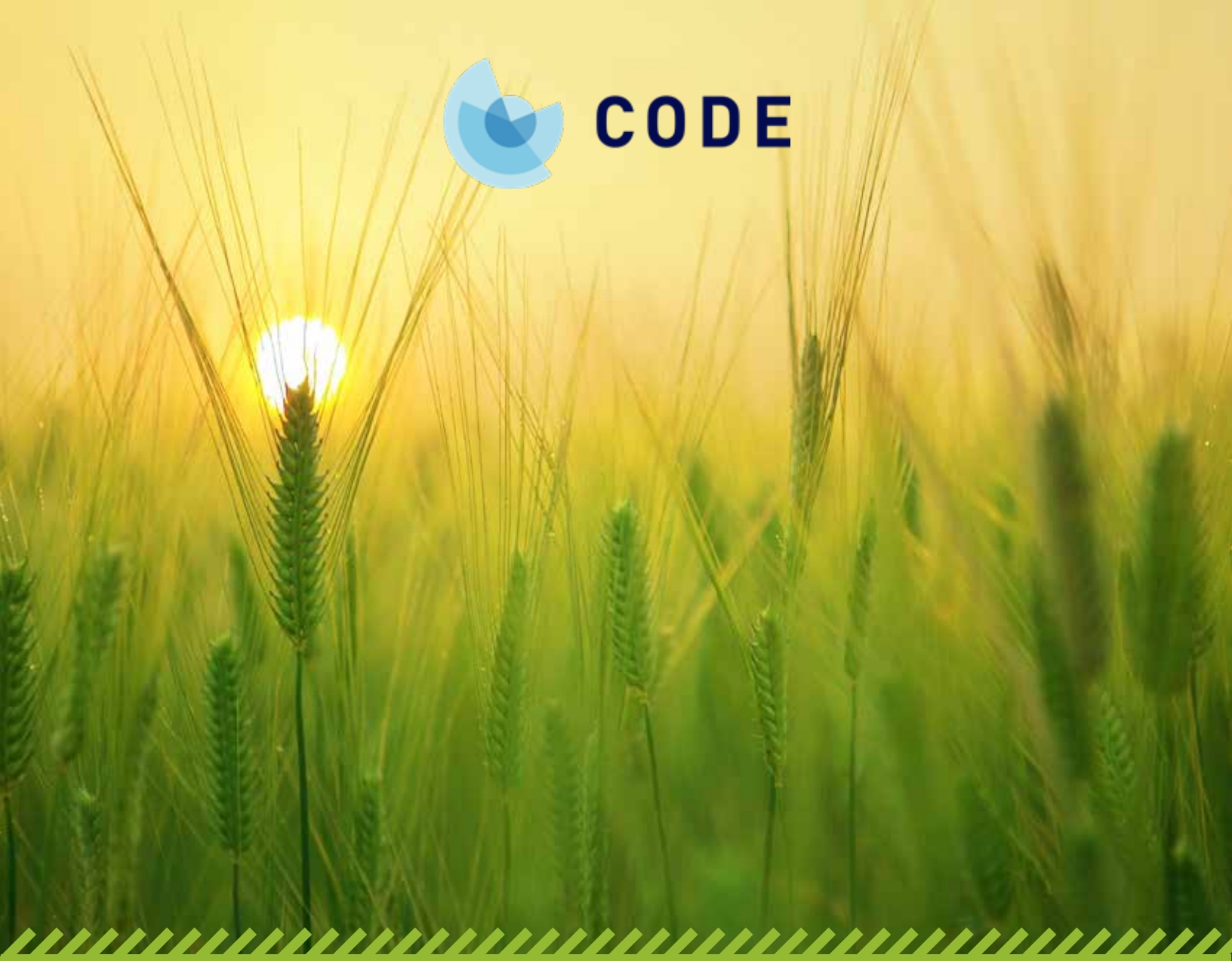

CODE

# LYME INNOVATION ROUNDTABLE

## Summary Report

Updated May 2019

# Contents

# Acknowledgments

The Lyme Innovation Roundtable was made possible by the Office of the Chief Technology Officer of the U.S. Department of Health and Human Services, the Steven & Alexandra Cohen Foundation, the Bay Area Lyme Foundation, Ensemble, and the Center for Open Data Enterprise. Special thanks to the co-organizers of the Lyme Innovation Roundtable, including Kristen Honey, Ed Simcox, Wendy Adams, Bennett Nemser, Adam Karides, Mike Contreras, Joel Gurin, Katarina Rebello, and Jacob Lewis.

We also acknowledge the many government agencies that participated in this Roundtable. Thanks to the Executive Office of the President Office of Management and Budget, the U.S. Army Public Health Center, the Armed Forces Pest Management Board, and the Congressionally Directed Medical Research Programs' Tick-Borne Disease Research Program within the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Participating offices and operating divisions within the U.S. Department of Health and Human Services included the Agency for Healthcare Quality and Research, the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the Immediate Office of the Secretary, the National Institutes of Health, the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Preparedness and Response.

For a full list of participating organizations beyond government agencies, please see Appendix 3.

This report is produced by the Center for Open Data Enterprise. It is not a U.S. government report. Information and opinions in this report do not necessarily reflect the opinions of each participant of the Lyme Innovation Roundtable, the U.S. Department of Health and Human Services, or any other component of the federal government.

# Executive Summary

On December 4, 2018, the Office of the Chief Technology Officer (CTO) at the U.S. Department of Health and Human Services (HHS) hosted the first-ever Lyme Innovation Roundtable. This Roundtable broadly defined "Lyme disease" to include acute Lyme disease, chronic Lyme disease, post-treatment Lyme disease syndrome (PTLDS), and other tick-borne diseases that may co-occur with Lyme disease.

The Roundtable convened over 80 experts from government, industry, academia, clinical research institutions, patient advocacy groups, nonprofits, and philanthropic organizations. The purpose of the Roundtable was to harness the power of collaboration, data-driven innovation, and emerging technologies for Lyme and tick-borne diseases. Participants discussed and provided individual input on how to advance the field. The event included input from patients and caregivers with lived experience, as well as from medical practitioners, scientific researchers, and policy makers working on the U.S. response to tick-borne diseases.

At each table, approximately 10 participants focused on one of four table themes:

**Prevention** Take measures and embrace a portfolio of strategies to reduce the incidence of Lyme disease, such as more effective outreach and communication strategies to improve public awareness.

**Diagnosis** Improve diagnostic tests and tools to ensure that infected individuals are quickly identified, properly diagnosed, and treated for the appropriate tick-borne disease(s) before they suffer serious *sequelae*.

**Treatment** Foster a patient-centered, value-based healthcare system where patients have access to affordable and effective medical care, including treatment options and innovative therapeutics guided by the latest scientific understanding, individualized patient data, and experimental therapies or clinical trials with informed consent.

**All Hazards** Extend the "All Hazards" approach to clinical-decision support for Lyme disease and tick-borne conditions, using existing infrastructure and electronic health records (EHRs) to share near-real-time information with bidirectional information exchange between HHS and the U.S. states, local public health communities, the healthcare establishment, and consumers.

## Key Takeaways

Roundtable participants identified the need for increased federal leadership with a national strategy and coordination for Lyme and tick-borne diseases. Many participants recommended that the HHS Secretary establish a national coordinating office for tick-borne conditions. This new office would ideally have broad, crosscutting authority to promote emerging technologies, innovation, and public-private partnerships. It would be the first office in HHS to holistically address tick-borne conditions across all operating divisions. Participants emphasized the need for interdisciplinary collaboration with federal leadership to break down existing silos and strategically execute a national strategy across federal, state, and local government, academia, industry, and all sectors.

Individual participants also emphasized the need to build trust — with trust defined as consistency over time — between the government and stakeholders. Trust-building may be done through increased stakeholder engagement, as well as by including patients in the scientific research and policy processes. Patients welcomed opportunities to be involved in clinical trials, which would require increased federal budgets for clinical trials research and experimental therapies for tick-borne diseases. Many recommended augmenting conventional scientific research with patient-powered research (e.g., patient registries), crowdsourcing, citizen science, and innovative public-private partnerships.

Participants encouraged HHS to leverage existing public-private partnerships and forge new collaborations to drive innovation and accelerate solutions for the prevention, control, and cure of tick-borne conditions. Future partnerships must prioritize data interoperability, data sharing, and emerging technologies such as artificial intelligence (AI) and "deep medicine" (Topol, 2019) in order to scale information and insights across different organizations. Strategic investments in data infrastructure — including data governance and data ethics — will help identify complex patterns for new insights into tick-borne diseases.

Participants identified the following opportunities for HHS and other stakeholders to improve their understanding of and response to Lyme disease and other tick-borne conditions.

### Cross-Cutting Priorities

- Increase Congressional appropriations and federal budgets for tick-borne conditions.
- Leverage existing infrastructure for tick-borne disease research.
- Improve coordination with a national strategy for Lyme and tick-borne disease research inside and outside the federal government.
- Improve access to high-quality, interoperable data to enable emerging technologies.

### Prevention

- Improve the collection and public dissemination of data about ticks and tick-borne conditions.
- Encourage active vector control.
- Enable the development of safe and effective vaccines.

### Diagnosis

- Communicate updated information about Lyme and tick-borne diseases to health care providers.
- Improve the quality and reliability of diagnostic tools and tests.

### Treatment

- Improve the quality of patient care through better data sharing and data use.
- Share data equitably and ethically with research participants.
- Reinstate a resource library for guidelines and case definitions.

### All Hazards

- Develop a data-driven, standardized process to address tick-borne conditions.
- Integrate a tick-borne disease "use case" into the All Hazards infrastructure integrated with EHR data.
- Develop standardized screening protocols for tick-borne conditions, customized by geographic region.

This report, prepared by the independent Center for Open Data Enterprise (CODE), represents a summary of the Lyme Innovation Roundtable participants' discussions of these issues, research related to the Roundtable, and post-Roundtable discussions with several participants. The proposed next steps presented in this report are based on individual input and recommendations from those discussions and are not meant to represent a formal consensus of the group.

# Roundtable Overview

The HHS Office of the CTO hosted the first-ever Lyme Innovation Roundtable on Tuesday, December 4, 2018, in the Great Hall at HHS headquarters, Washington, D.C. The Roundtable was made possible with support from the HHS Office of the CTO, the Steven & Alexandra Cohen Foundation, the Bay Area Lyme Foundation, Ensemble, and the Center for Open Data Enterprise (CODE). This Roundtable broadly defined "Lyme disease" to include acute Lyme disease, chronic Lyme disease, post-treatment Lyme disease syndrome (PTLDS), and other tick-borne diseases that may co-occur with Lyme disease.

## Ground Rules

The Lyme Innovation Roundtable was an invitation-only event designed to elicit individual views and suggestions from patients and experts in the field. Participants joined for a one-time event, not as a regular group, and were not expected to reach consensus on topics of discussion, so Federal Advisory Committee Act (FACA) rules were not applicable to this convening. Similarly, FACA rules do not apply to this report authored by CODE. Comments by individual Roundtable participants have been taken as suggestions, rather than as formal recommendations, for this public report.

Discussions at the Lyme Innovation Roundtable were held under the Chatham House Rule. At a meeting held under the Chatham House Rule, anyone who attends is free to use information from the discussion but is not allowed to reveal who made any comment. It is designed to build trust and increase openness of discussion.

## Purpose and Structure of the Day

The shared purpose of the day was to harness the power of collaboration, data-driven innovation, and emerging technologies for Lyme and tick-borne diseases. The agenda and participating organizations for the Roundtable are found in Appendices at the end of this report.

HHS livestreamed the Roundtable opening session and has posted the video online for public viewing. The day opened with remarks from the HHS CTO, Ed Simcox, whose office hosted the Roundtable. The HHS Deputy Secretary, Eric Hargan, delivered the opening keynote on advancing science and partnerships for patient-centered care. Adam Boehler, Director and Deputy Administrator for Innovation and Quality with the Centers for Medicare and Medicaid Services (CMS), emphasized patient-focused innovation as the next frontier of healthcare. Robert Redfield, the Director of the Centers for Disease Control and Prevention (CDC), helped to kick off the afternoon session with a pre-recorded video presentation on coordinated strategy and collaboration for Lyme and tick-borne diseases. These remarks were followed by invited presentations on patient-centered healthcare innovation, lightning talks, and action-oriented breakout sessions.

Three breakout sessions involved hands-on, interactive exercises to connect diverse stakeholders with each other in groups that remained at the same breakout table throughout the day. During these breakout sessions, Roundtable participants provided their input to:

1. Identify priorities and available resources from all sectors, including datasets, research methodologies, and tools.
2. Explore and scope opportunities for collaboration, public-private partnerships, and data-driven innovation to address Lyme disease.

Each Roundtable participant was assigned to a table for breakout sessions on one of four thematic areas:

**Prevention** Take measures and embrace a portfolio of strategies to reduce the incidence of Lyme disease, such as more effective outreach and communication strategies to improve public awareness.

**Diagnosis** Improve diagnostic tests and tools to ensure that infected individuals are quickly identified, properly diagnosed, and treated for the appropriate tick-borne disease(s) before they suffer serious *sequelae*.

**Treatment** Foster a patient-centered, value-based healthcare system where patients have access to affordable and effective medical care, including treatment options and innovative therapeutics guided by the latest scientific understanding, individualized patient data, and experimental therapies or clinical trials with informed consent.

**All Hazards** Extend the "All Hazards" approach to clinical-decision support to Lyme disease and tick-borne conditions, using existing infrastructure and EHRs to share near-real-time information with bidirectional information exchange between HHS and the U.S. states, local public health communities, the healthcare establishment, and consumers.

The All Hazards approach involves developing robust data-driven systems that can be used to track, respond to, and recover from disease outbreaks, epidemics, and other emerging threats. The All Hazards approach begins with a clinically relevant event — for example, when a public health agency identifies a population at risk, or when an individual goes through a medical screening procedure. Then the All Hazards infrastructure is used to push out the latest scientific information and clinical recommendations, which practitioners experience as part of their EHR systems. Lastly, anonymized data from the clinic and field are shared with HHS and the All Hazards infrastructure to improve future iterations and information accuracy.

The Roundtable concluded with a Presentation of Highlights from the breakout sessions emceed by Colonel Nicole Malachowski, United States Air Force (Ret.). Each breakout table shared a summary of insights and suggestions for the audience, including an elevator pitch for senior leadership in response to the following question:

***"If you had three minutes with the HHS Secretary, what near-term actions would you propose to transform the landscape of tick-borne disease prevention, diagnosis, and treatment?"***

The end of the day featured the need for cross-sector collaborations by having the trifecta of government, philanthropy, and non-profit organizations share one stage. Bennett Nemser, Senior Program Officer of the Steven & Alexandra Cohen Foundation, emphasized the need for collaborative solutions and federal leadership. Wendy Adams, Research Grant Director of the Bay Area Lyme Foundation, also spoke to the need for increased HHS priority and federal scientific R&D for tick-borne diseases. Together with Dr. Kristen Honey, Innovator in Residence with the HHS Office of the CTO, they emphasized how today's challenges with tick-borne conditions require "all hands on deck." Public-private partnerships and collaborations, such as this Roundtable, are one way to catalyze action and expedite systemic change by working together on the many complex challenges posed by Lyme disease and tick-borne conditions. This Roundtable is a first step to ongoing collaborations with leadership commitment from all sectors.

Following the Roundtable, CODE drafted this summary report. This public report provides an overview of the Roundtable discussions and follow-up discussions with several participants, including the top priorities identified and actionable next steps that can be taken to address Lyme disease and tick-borne conditions.

# Background

## Understanding Lyme and Tick-Borne Disease

Lyme disease, the most common tick-borne illness in the United States, is an infectious disease caused by the bacterium *Borrelia burgdorferi* and transmitted primarily through tick bites. One of the most well-known symptoms of the disease is the *erythema migrans* (EM) or "bullseye" skin rash, though skin rashes vary and do not occur in all infected persons. Other early symptoms of the disease can include fever, chills, headache, fatigue, and muscle and joint aches (TBDWG, 2018, p. 58). Without timely diagnosis and treatment, Lyme disease symptoms can worsen and cause arthritis, facial palsy, brain and spinal cord inflammation, or short-term memory loss, and can potentially be fatal. Lyme carditis, for example, is an uncommon yet extremely serious and potentially fatal condition which arises when the *B. burgdorferi* bacteria enter the tissues of the heart (CDC, 2018a).

Lyme disease may be the most visible yet it is far from the only tick-borne condition. The CDC currently recognizes 18 tick-borne pathogens affecting human health in the United States (TBDWG, 2018, p. 1). Experts continue to discover new disease agents and medical conditions associated with tick bites. For example, alpha-gal syndrome (i.e., the "meat allergy") was overlooked until the 21st century. In addition, introduced tick species pose new risks. For example, the exotic Asian longhorned tick (*Haemaphysalis longicornis*) first appeared in the continental United States in 2017. The Asian longhorned tick is known in other parts of the world to carry a virus that causes severe fever with *thrombocytopenia syndrome* (SFTS), an emerging hemorrhagic fever discovered in China. The scope and scale of tick-borne disease challenges continue to grow.

## U.S. Challenge with Lyme Disease

Lyme disease is a public health priority that affects hundreds of thousands of people every year in the United States alone. As noted in the recently published Tick-Borne Disease Working Group (TBDWG) 2018 report, several barriers impede a coordinated, nationwide response and solutions. U.S. challenges include:

**Low Levels of Public Funding and Leadership.** Lyme and other tick-borne diseases are a growing concern in the United States, but funding for treatment and research remains relatively low. For example, there are almost as many annual reported cases of Lyme disease in the U.S. as there are of HIV/AIDS (36,000 new cases vs. 39,000 new cases). Yet combined spending on Lyme disease from the CDC and NIH was only one-tenth as much in 2017: $39 million vs. $3.8 billion. Moreover, because experts believe that Lyme disease is greatly underreported with the actual number of U.S. cases over 300,000 each year (Rosenberg, 2018), this funding discrepancy per case is even more pronounced.

**Challenges with Nomenclature and Disease Definition.** The lack of agreed-upon nomenclature for Lyme disease continues to inhibit scientific research, diagnosis, and patient care. For example, clinicians and researchers do not have consensus about what to call the long-term effects of Lyme disease. Some call it "tertiary" Lyme disease, or "late-stage" Lyme disease, which can also refer to an infection that goes undiagnosed for some time. Individuals who are not in clinical research — including patients and advocates — generally prefer the term "chronic Lyme" disease to describe those who continue struggling with long-term, Lyme-like symptoms even after a short course of antibiotic treatment for Lyme disease. At this time, however, no clinical or research definition exists for chronic Lyme disease so researchers cannot study or conduct clinical trials on this undefined condition.

In an effort to help align patient experiences of chronic Lyme disease with the research on Lyme disease, medical researchers narrowly scoped one subset of chronic Lyme disease and clinically defined it as "Post-Treatment Lyme Disease Syndrome" (PTLDS) (Aucott, 2015). The clinical definition of PTLDS is often misunderstood and misused beyond its intended research purpose. PTLDS does not replace — nor is it the same as — the term chronic Lyme disease. Rather, it is a clinically defined subset of chronic Lyme patients that can be researched with clinical trials.

Diverse stakeholders may not yet agree on terms to use, yet there is widespread agreement that individuals with persistent symptoms are legitimately ill and in need of medical care to have their health restored (TBDWG, 2018, p. 78). Until shared understanding exists for key words and concepts in Lyme disease, however, it is extremely challenging to work across stakeholder groups and disciplines.

**Outdated Diagnostic Tools and Methods.** Existing diagnostic tests for Lyme disease use decades-old technologies that cannot accurately detect an infection during all stages of Lyme disease. Available tests are antibody-based ("serological") and detect only the patient's immune response to the pathogen, not the existence or quantity of the pathogen itself. They do not indicate whether the bacterial infection is active.

Scientific uncertainty, and some would say unreliability, of currently available diagnostic tests are a strong disincentive for private-sector investment in Lyme disease R&D. Without accurate diagnostics to detect an active infection, it's difficult to agree who has Lyme disease or to test and evaluate treatment efficacy.

A further complication is the misuse of the surveillance case definition for Lyme disease. A surveillance case definition is designed to be a set of uniform criteria used for public health surveillance, and is not supposed to be used to diagnose individual patients (TBDWG, 2018, p. 20). The surveillance criteria for Lyme disease require a "two tiered positive" test, including a positive or equivocal enzyme-linked immunosorbent assay (ELISA) followed by a positive Western blot (WB) test. According to the CDC, these criteria may not include many people who have the disease (CDC, 2018b). However, because many doctors and scientists are unaware of this distinction and use the surveillance criteria for diagnosis, patients who are infected are often told incorrectly that they do not have Lyme disease.

**Barriers to Effective Treatment.** Health care providers commonly prescribe treatment regimens for Lyme disease in a "one size fits all" approach. However, the treatment of tick-borne illnesses is complex due to a diversity of individual factors that must be considered. In addition, treatment guidelines vary. Lyme treatment guidelines from the Infectious Diseases Society of America (IDSA) call for short-term antibiotic therapy. IDSA emphasizes the need for evidence-based medicine to treat the properly diagnosed condition, which can be challenging given available diagnostic tests and limited R&D for repeatable scientific studies with Lyme disease. Another set of guidelines from the International Lyme and Associated Diseases Society (ILADS) emphasizes that the response to Lyme disease treatment often depends on the strains of bacteria found, duration of illness, presence of other tick-borne pathogens, and other underlying health issues.

Adding to these challenges, many symptoms attributed to Lyme disease do not develop immediately and overlap with other medical conditions, including behavioral and psychiatric symptoms. Lyme disease can look like many other diseases, which is why some call it "The Great Imitator". At the same time, ticks can also transmit other pathogens, which increases the likelihood of misdiagnosis.

## Using Data to Address Lyme Disease

Data is a critical resource and a strategic asset that can be used to address the many complex issues surrounding Lyme disease. Faced with limited federal leadership and public funding, non-governmental stakeholders have mobilized in recent years to harness the power of data and innovation for next-generation solutions (see textbox on next page). Much work remains, however, regarding the need for data interoperability, standards, governance, and ethics across studies and organizations. Government, industry, academia, and the broader research community must lead on these issues, which are a prerequisite for big data to scale and become a powerful tool to combat Lyme and tick-borne diseases.

**Examples of data-driven innovation with the potential to improve Lyme disease diagnosis, treatment, and prevention include the following.**

Clyme Health is a private company focused on improving the lives of people living with Lyme disease and other invisible illnesses by capturing diagnostic and treatment experiences, surfacing insights, and sharing results to improve treatment for individuals and the collective whole.

Geisinger is a physician-led healthcare system that is analyzing more than 500,000 electronic medical records together with geolocation data to understand the risk of Lyme disease in vulnerable populations. In collaboration with Johns Hopkins University, Geisinger is investigating how patients get Lyme disease as well as relevant vulnerabilities, risks, and delays they may face in receiving care.

LymeMIND is a predictive model of Lyme disease, which leverages a network of collaborators sharing data to help identify novel biomarkers and new therapeutic opportunities. Through molecular profiling, this systems-medicine approach applies advanced statistical and machine learning techniques to improve our understanding of Lyme disease.

MyLymeData is LymeDisease.org's survey tool that tracks progress over time for patients with Lyme disease. With over 11,000 participants enrolled, it allows patients to use today's technology to quickly and privately pool diagnosis and treatment experiences. Combining large amounts of data makes it possible to see patterns that help determine which treatments work best.

Lyme Disease Biobank (LDB) is a collection of human biological samples with associated clinical information created to help investigators studying Lyme disease and other tick-borne infections. Samples are available to researchers and companies creating new diagnostic tests and working to better understand this complex disease. LDB is also partnering with the National Disease Research Interchange (NDRI) and the MyLymeData Registry to collect tissue samples and detailed information from people with Lyme disease. LDB is a type 1 supporting organization of Bay Area Lyme Foundation.

TickTracker is a mobile app that helps users report and track ticks in real time. Based on this real-time tracking and several other data sources, the app enables users to view the tick severity index in their area. The app also includes information on how to safely remove ticks and how to be proactive in helping prevent tick bites.

## Public-Private Collaborations to Accelerate Change

Public-private collaborations and partnerships are not an end in and of themselves, but focused on clear goals and objectives, they can be an expedient way to spur the next generation of solutions for Lyme and tick-borne diseases. The HHS Office of the CTO is uniquely positioned to lead in this regard. The Office of the CTO tackles complex challenges—including Lyme disease—with strategies that leverage the power of open data, open science, crowdsourcing, citizen science, prizes, challenges, and innovative public-private partnerships. The America COMPETES Reauthorization Act of 2010 provides clear legal guidance for the HHS Office of the CTO to use appropriated funds towards the use of challenges and prize competitions as a tool for innovation.

**Public-private collaborations and partnerships at HHS serve as models for Lyme and tick-borne diseases. Examples of such innovation by the Office of the CTO and other HHS divisions include the following:**

Biomedical Advanced Research and Development Authority (BARDA) DRIVe is an initiative to "Accelerate the development and availability of transformative technologies and approaches to protect Americans from health security threats." BARDA, an office within HHS, has launched DRIVe using new authorities under the 21st Century Cures Act to stimulate innovation. According to its website, DRIVe is using venture funding approaches to build "an ecosystem of restless innovation, driven by industry and the entrepreneurial community."

CARB-X is a non-profit public-private partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria. CARB-X is funded by BARDA and Wellcome Trust, a medical charity based in the United Kingdom. The National Institute of Allergy and Infectious Diseases (NIAID) provides preclinical services to CARB-X-funded research projects. In 2018, the CARB-X partnership welcomed two new funding partners: the UK Government's Department of Health and Social Care through its Global Antimicrobial Resistance Innovation Fund (GAMRIF), and the Bill & Melinda Gates Foundation. With more than $500 million to invest between 2016 and 2021, CARB-X is accelerating global antibacterial innovation by investing in the development of new antibiotics and other life-saving products to combat the most dangerous drug-resistant bacteria.

Kidney Innovation Accelerator (KidneyX) is a public-private partnership between HHS and the American Society of Nephrology to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. KidneyX is a $25 million series of prize challenges to redesign dialysis. It seeks to improve the lives of the 850 million people worldwide currently affected by kidney diseases by accelerating the development of drugs, devices, biologics and other therapies across the spectrum of kidney care. Building off the success of similar public-private accelerators, KidneyX challenges a community of researchers, innovators, investors, and problem solvers to develop breakthrough therapies. HHS CTO, Ed Simcox, has reaffirmed that initiatives like KidneyX can help "to 'de-risk' innovation by streamlining processes, reducing regulatory barriers, and modernizing the way we pay for treatment."

Million Hearts Initiative works with hospitals and other partners to implement high-priority approaches to fight heart disease, stroke, and related conditions. The Initiative was launched by CDC and CMS in 2012 to focus disease prevention efforts for public health and clinical benefit. Among other actions, the Initiative has worked to align Clinical Quality Measures on major goals – such as blood pressure, cholesterol, and weight management – so that both public and private institutions can track patient care and outcomes with the same metrics. This data-driven approach is instrumental to achieving the goal of preventing a million heart attacks and strokes in five years

Rare Diseases Are Not Rare! Challenge is an "innovation collaboration" designed to raise public awareness about rare diseases with prize winners announced in February 2019. The National Center for Advancing Translational Sciences (NCATS), part of the NIH, launched this challenge to crowdsource ideas from the public to raise awareness of rare diseases and support for research on them. Winners and runners-up included posters, videos, and a quiz. This prize challenge serves as a model for how campaigns might be developed for other types of diseases (e.g., tick-borne diseases) and public health concerns.

"TOP Health" tech sprint with the HHS Office of the CTO is a new pilot program modeled after The Opportunity Project (TOP) led by the Census Bureau at the U.S. Department of Commerce. TOP is a pioneering model for lightweight collaboration between government and the tech sector to tackle complex challenges using data, technology, and agile methods. In a recent 14-week tech sprint, the HHS Office of the CTO worked with tech teams on a challenge to "harness the power of collaboration, citizen science, and data for Lyme disease." The results for Lyme disease included TickTracker, an app that makes it possible to track and report ticks in real time using geolocation data with new heat maps; TickTickBOOM!, an edutainment-based game to help middle-school students have fun while learning tick awareness and prevention strategies; the Lyme Tracker app, which enables patients to track their symptoms and activity; and the Clyme Health app, which enables patients to track their symptoms and activity while sharing their health data with practitioners to visualize data over time and to manage complex conditions (Honey and Alterovitz, 2019; Alterovitz et al., 2019; Honey et al., 2019).

# Priorities for Addressing Lyme and Tick-Borne Diseases

Participants at the Lyme Innovation Roundtable identified their top priorities through discussions in three breakout sessions during the day. Depending on where participants sat by table theme, they focused their individual suggestions on one of the following:

- Prevention
- Diagnosis
- Treatment
- All Hazards

Participants also identified cross-cutting opportunities for HHS and other stakeholders to improve their response to and understanding of Lyme disease and other tick-borne diseases.

## Cross-Cutting Priorities

### Increase Congressional appropriations and federal budgets for tick-borne conditions

Roundtable participants expressed an urgent need to increase federal funding for Lyme and tick-borne diseases, to support research, treatment, and a national strategy to prevent, control, and ultimately cure tick-borne diseases. They recommended budget increases for tick-borne disease research across HHS, which could include budgets for BARDA, CDC, CMS, Food and Drug Administration (FDA), National Institutes of Health (NIH), Office of the Assistant Secretary for Health (OASH), and the HHS Office of the CTO. The Tick-Borne Disease Working Group similarly stressed the need for increased federal funding in its 2018 report to Congress. As that report noted:

> "*Increased federal funding, prioritization, and leadership are needed to reverse the alarming trends associated with tick-borne diseases. Federal funding for tick-borne diseases today is orders of magnitude lower, compared to other public health threats, and it has failed to increase as the problem has grown. It is also essential that funding and resources be allocated to support a comprehensive, interagency program to address the mounting challenges identified in this report*." (TBDWG, 2018, p. 3.)

Increased R&D funding for tick-borne diseases can come from several federal agencies and departments beyond HHS as well, because tick-borne conditions affect so many U.S. citizens. Other federal agencies may address tick-borne conditions as part of their mission-critical priorities. Roundtable participants and further discussions after the event identified the following federal agencies with capabilities and resources to help address tick-borne conditions:

- U.S. Agency for International Development
- U.S. Department of Agriculture
- U.S. Department of Defense
    - Armed Forces Pest Management Board
    - Defense Advanced Research Projects Agency (DARPA)
    - Global Emerging Infections Surveillance Section
- U.S. Department of Energy and National Laboratories
- U.S. Department of the Interior
    - National Information Solutions Cooperative
    - National Park Service
    - U.S. Geological Survey
- U.S. Department of Veterans Affairs
- U.S. Environmental Protection Agency

### Leverage existing infrastructure for tick-borne disease research

Data-driven solutions will be accelerated by repurposing existing infrastructure and expertise for tick-borne diseases. For example, the NIH's Models of Infectious Disease Agent Study (MIDAS) is an existing distributed framework of public health research institutions. MIDAS is prepared to conduct research on emerging threats from infectious diseases such as Zika, Malaria, and Dengue Fever, and could be used to address Lyme and tick-borne conditions. Other examples are the CDC Regional Centers of Excellence (COE) in Vector-Borne Diseases, created in 2017 in response to the Zika virus outbreak. For this to happen, Congress must fund the existing CDC COEs beyond 2021 (when current appropriations end) with direction to prioritize tick-borne diseases.

Roundtable participants recommended establishing an interagency data-driven consortium, similar to the one that launched the Human Genome Project, for a 21st Century "Manhattan Project" with Lyme and tick-borne diseases. Participants welcomed the idea of a joint agreement between NIH and the U.S. Department of Energy (DOE) National Laboratories, analogous to how basic science from DOE and the National Laboratories advanced genomic and systems biology to sequence human DNA. Such an interagency collaborative could unlock additional R&D funds, computing capacity, and cross-disciplinary discoveries from DOE National Laboratory capabilities. DOE core competencies to augment HHS and NIH efforts include:

- Advancing an ecosystems approach to understanding and predicting the emergence of tick-borne pathogens.
- Elucidating fundamental organizing principles of microbiome architectures in vertebrates and arthropods.
- Identifying and quantifying ecological solutions for the management of tick-borne disease.

### Improve coordination with a national strategy for Lyme and tick-borne disease research inside and outside the federal government

Roundtable participants articulated how a powerful federal consortium would include collaboration across four agencies: HHS, the DOE National Laboratories, the U.S. Department of Defense (DOD), and the U.S. Department of Veterans Affairs (VA). Such a collaboration could be piloted through a joint agreement between HHS and DOD, specifically the BARDA and DARPA programs, to accelerate the development of transformative technologies and innovations to protect Americans from tick-borne diseases. HHS has an overriding interest in protecting civilians and public health, while the DOD has a similar mission for the health of service members and military families. DOE National Laboratories have extensive resources to study the interaction of ticks and bacteria and do predictive modeling of disease patterns. The VA cares for the health of American Veterans and their families. Together, working across all four missions with strategic coordination, federal government could significantly move the needle on tick-borne diseases.

Coordinated research under one national strategy would create valuable, publicly available information on many important aspects of Lyme and tick-borne diseases. This kind of coordination should leverage existing infrastructure and resources across academia, industry, and all levels of government: federal, state, and local. The private sector and philanthropy can augment funding amounts and add available resources to further expand networks of data-driven centers under one coordinated strategy across all 50 states.

Roundtable participants from all fields, including academics, health care providers, and patient advocates, emphasized the need for coordinated exploratory research that could lead to critical advancements like improved diagnostic tools and the development of safe and effective vaccines. They cited the need to improve our understanding of different bacterial strains that cause Lyme disease, including spirochetal, round-body, and persister forms. Some Roundtable participants also recommended expanding research to include secondary concerns with potential high impact, such as the role played by tick saliva in the transmission of the pathogen.

### Improve access to high-quality, interoperable data to enable emerging technologies

The next advances in research, treatment, and diagnosis of Lyme and other tick-borne diseases will increasingly be driven by data. Many Roundtable participants recommended improving access to high-quality tick-borne disease data with interoperable national standards, including data available for analysis in biorepositories. Biorepositories refer to the physical storage of biological and environmental samples, including but not limited to blood and tissue, sourced through public health surveillance programs. They may be funded and driven by government agencies or non-government organizations. Biorepositories for tissue and blood samples, such as those maintained by the CDC, NIH, DOD, and the Bay Area Lyme Foundation, should include samples from patients with Lyme disease—as well as biological data from uninfected individuals—over time with rigorous regulatory standards for quality control.

Longitudinal data will help identify changes to the human body after infection has occurred, and can help scientists, practitioners, and diagnosticians track the progress of Lyme and other tick-borne diseases over time. This will provide critical information about the development of the infection, comorbidity with other infections, and the scientific basis for long-term effects of Lyme disease. These repositories are crucial for providing researchers with real world patient samples and endemic controls to test novel diagnostic technologies and ascertain their sensitivity and specificity for potential commercialization.

To ensure that data is responsibly accessed and used, data standards and interoperability are essential. Such work is being advanced by various HHS Operating Divisions, including the CMS Blue Button 2.0. Yet Lyme and tick-borne disease stakeholders emphasized the higher-resolution data interoperability across all the disciplines of personalized medicine, as well as the need for data ethics and informed consent by patients, especially patients who contribute data for research. Shared decision-making is essential so that the risks and benefits of treatment alternatives are evaluated collaboratively between the patient and physicians.

Researchers also need improved access to big data analytic tools and machine learning capabilities. Emerging analytical methods, including AI, increase our ability to recognize subtle patterns in data that in time will enhance the ability to diagnose and treat. More collaborations with DOE National Laboratories and academic institutions with High Performance Computer Clusters (HPCC) could help accelerate AI and emerging technologies to help address tick-borne diseases. Roundtable participants noted that there may be opportunities to use distributed ledger technologies for data quality assurance. Opportunities exist to publicly showcase the real-world applications of data-driven technologies and innovation for American health, for example, through HHS CTO Startup Days, National Day of Civic Hacking, The Opportunity Project, and the annual Health Datapalooza.

## Prevention

### Improve the collection and public dissemination of data about ticks and tick-borne conditions

In order to reduce the likelihood of tick bites and infection, participants emphasized the importance of designing effective public service announcements (PSAs), social media campaigns, and informational materials that could be used to improve awareness of the growing threat of tick-borne diseases and ways to prevent them. Roundtable participants pointed to successes in communicating about other infectious diseases, including HIV/AIDS, Zika, and malaria. Similar approaches could be taken to educate the public about Lyme and tick-borne disease.

Since many sources of information about Lyme and tick-borne disease already exist, it will be important to identify available resources and assess the quality of existing resources. Participants supported the idea of an index of available resources, which are of sufficient quality and up to date, before creating new informational materials and programs. An index of available resources could include information about the potential for safe and effective vaccines currently under development, as well as document concerns and

questions about vaccines previously available for humans. Cataloging existing information — particularly information that is open to public use — can provide an important resource to improve prevention and detection of Lyme disease. This information can be disseminated through existing channels such as state and local health departments, national parks, and school systems.

Using new technologies can help improve public awareness and give parents and schools around the country important information about Lyme and tick-borne diseases. This can include information about the prevalence of ticks in their geographical area, ways to guard against tick bites, and ways to detect Lyme and other tick-borne disease. Participants noted the potential for developing and/or improving mobile apps to deliver this information, which could include real-time tick tracking reports modeled after real-time influenza reports.

As an example, the TickTracker app provides important information about tick surveillance, safely removing ticks, and proactive prevention. The app allows for real-time tick reporting to improve surveillance data that can be fed into publicly available datasets for use by doctors, patients, and researchers. School-aged children and parents can also use tick-awareness games in mobile apps to learn about Lyme disease.

### Encourage active vector control

Information and educational campaigns should focus on encouraging citizens — particularly those in areas with large tick populations — to use Environmental Protection Agency (EPA)-registered insect repellents to minimize the chance of tick bites. Participants suggested treating clothing with repellents that include the chemical Nootkatone, which is classified by the CDC as a biopesticide. According to the CDC, "Nootkatone appears to work differently compared to currently available insecticides and may be a valuable new option for fighting the growing problem of insecticide resistance in mosquitoes. It can be used on skin and lawns. To expand available insect repellent options, Nootkatone could be formulated to be used in soaps, sprays, and lotions."

### Enable the development of safe and effective vaccines

Finally, participants emphasized the importance of finding and developing safe and effective vaccines for Lyme and tick-borne diseases. Vaccines for Lyme disease have existed in multiple forms for decades. In the 1990s, researchers developed a vaccine that the manufacturer withdrew from production in 2002 following a series of class-action lawsuits, citing low demand for the vaccine. Recent research has begun to examine new formulations that remove specific chemical components (e.g., hLFA-1 epitope), which researchers suspected might cause arthritis (CDC 2018c). Currently, researchers in France are in the process of developing a Lyme disease vaccine that meets these criteria. Federally funded science must prioritize vaccine research with emphasis on the need for rigorous testing to document both the safety and the efficacy of future vaccines.

Roundtable participants suggested that future vaccine research should focus on examining individuals with potential immunity or resistance to Lyme disease to determine what biological factors may help protect them. Concerns about vaccines are understandably high, given past experience, and participants emphasized the importance of developing safe and effective vaccines. They also noted that vaccine research should not be funded at the expense of support for diagnostic and treatment advances that can help those who are already infected.

Roundtable participants also expressed interest in a "tick vaccine" to target tick proteins that would reduce tick feeding, reproduction, and transmission of tick-borne pathogens. Such a tick vaccine would protect against Lyme disease as well as other tick-borne pathogens.

# Diagnosis

### Communicate updated information about Lyme and tick-borne diseases to health care providers

Delay in diagnosis is a risk factor for developing persistent symptoms even after initial treatment of Lyme disease. Participants emphasized the need to make more high-quality data and information available to physicians to expand awareness of tick-borne diseases, including the many ways that Lyme disease manifests. Because Lyme disease does not always cause consistent physical symptoms, physicians would benefit from updated information about how to diagnose the disease and the reliability of existing diagnostic tests at all stages of the disease.

Health care providers should have access to more information about the potential presence of infection even without common Lyme disease markers such as EM lesions (i.e., a "bullseye" rash), and without positive results on diagnostic blood tests. Negative test results cannot rule out the possibility of infection with Lyme disease. Not all patients will test positive, even with severe disease (Halperin et al., 2013).

Because physicians should take factors other than the standard diagnostic tests into account, participants suggested giving physicians geo-sensitive data about the prevalence of tick-borne pathogens in states, counties, and neighborhoods. With such data, for example, doctors in New Hampshire and doctors in Alabama would each receive public health information related to their respective state, and doctors within the same state could tailor their assessment of risk based on where a patient lives, works, recreates, or travels. Combining geographic data with patient information can provide personalized patient risk profiles. Such profiles could alert physicians and patients to the geo-specific risks of Lyme and tick-borne diseases.

Roundtable participants recommended creating a comprehensive and inclusive database that health care providers can populate with case reports on patients with Lyme and tick-borne diseases. This database could be made available to researchers and other health care providers, and should include cases that fit existing CDC Case Definitions as well as those that do not. When testing for and diagnosing Lyme disease, health care providers should inform patients about the opportunity to contribute biological samples to the CDC's common biorepository to improve the quality and amount of data available, as well as asking for permission to include their case reports in the proposed database. This would help researchers analyze the sensitivity and accuracy of existing and newly developed diagnostic tests.

### Improve the quality and reliability of diagnostic tools and tests

Participants emphasized the need for diagnostic tools that directly measure tick-borne pathogens instead of testing for immune responses to Lyme disease. Such tools would improve future research by developing and identifying a "gold standard' diagnostic, meaning a technology to isolate and culture *B. burgdorferi* to confirm diagnosis (Marques, 2015). This would greatly assist in confirming diagnoses of Lyme disease. Roundtable participants identified this gold-standard diagnostic as being "game changing" and critical to future work. Improved diagnostics would rapidly advance the field and scientific understanding of Lyme disease, while also improving clinical practices and patient outcomes.

Current discrepancies and challenges to accurate diagnostics remain problematic in part because "[t]here are many difficulties in the interpretation of results from these studies, due to the lack of a gold standard, the use of different case definitions, different assays and interpretative criteria, retrospective evaluation, and little comparison among assays and among laboratories" (Marques, 2015). Current serology tests for Lyme disease are often unable to identify infection at all stages. They may not be able to detect strains that do not occur in the Northeast. As a result, recently infected individuals may not be diagnosed or receive the care they need for early intervention.

Third-party diagnostic tests developed by private-sector medical research labs should also be improved, for example, by voluntarily meeting FDA requirements and other federal regulations to assess the quali-

ty, sensitivity, and specificity of tests. While some tests are more sensitive than others in detecting Lyme disease, many are inaccurate, potentially leading to dangerous treatment plans and diagnoses. There is no standardized set of qualifications that third-party diagnostic companies must meet before advertising and selling diagnostic tests. As a result, third-party companies vary substantially in the levels of documentation and proof of efficacy they provide to state health boards. Third-party diagnostics should be tested more rigorously to protect consumers, and the labs that develop them should participate in clinical trials to measure the quality and accuracy of diagnostic tests for Lyme disease.

## Treatment

### Improve the quality of patient care through better data sharing and data use

Participants recommended sharing more data to improve diagnosis and treatment for patients at all stages of Lyme disease. More available, shared data could help overcome two obstacles to accurate diagnosis and effective treatment. First, existing diagnostic tools can miss early-stage and late-stage Lyme infections, since they do not test directly for the Lyme pathogen. Second, current diagnostic approaches do not incorporate information about symptoms reported by patients, which raises the risk of overlooking cases of infection, particularly in late-stage Lyme disease.

Shared data can help researchers develop new approaches to diagnosis and treatment based on a shared understanding of the disease. Roundtable participants emphasized the importance of sharing genomic data and data on other possible biomarkers related to Lyme disease, which can help diagnose the disease and tailor treatment to the individual. Sharing symptomatic data across many cases over time could also help researchers better understand how Lyme disease manifests and presents itself. Currently, most data on Lyme and tick-borne diseases focuses on the presence of serological evidence and excludes symptomatic data that could potentially improve longitudinal analysis of the disease.

### Share data equitably and ethically with research participants

Roundtable participants stressed the importance of data ethics, trust, and how research data are shared with the subjects of research on Lyme and tick-borne diseases. Patients with difficult cases may be highly motivated to join research efforts that can contribute to new diagnostics and therapies. These individuals should also be able to benefit from whatever researchers learn about them, including having copies of data from their genome or tissue analysis. That way, if they participate in future research studies with different investigators, both they and researchers can benefit from data that is known about them and their illness.

Participants discussed how HHS can advance participant-centered research practices, for example, by clarifying how CMS interprets the law governing laboratory standards and data sharing. At the request of CMS, FDA, and NIH, the National Academies of Sciences, Engineering, and Medicine published a report on how to share laboratory results with the research participants who provided the human biospecimens used in the lab (National Academies, 2018). The Academies' report interprets the governing laboratory standards — the Clinical Laboratory Improvement Amendments of 1988 (CLIA) — as CMS prohibiting any communication about research results (e.g., uninterpreted data) to participants, unless it is a CLIA-certified laboratory with special certification that allows it to do so. This restrictive interpretation of CMS rules has caused research institutions to restrict participant access to their own laboratory results, since institutions are concerned about legal risk.

However, there is a legal argument that CMS does not have the statutory authority for this restriction, and that this narrow definition may be a misinterpretation of the intended CMS position (Wolf and Evans, 2018). Roundtable participants recommended that HHS re-evaluate and clarify its CMS rules surrounding how patients may access their own laboratory results. HHS and CMS policy guidance is needed to enable researchers to share data with study participants, and enable patients to participate in research as equal partners.

### Reinstate a resource library for guidelines and case definitions

Roundtable participants recommended reinstating a publicly available resource library for diagnostic and case definition guidelines about Lyme and tick-borne diseases. Such a centralized repository, similar to the National Guideline Clearinghouse (NGC) that was taken down due to lack of funding in July 2018, could be supported by federal government or a third-party organization. Such a resource library would be a neutral repository with clearly defined inclusion criteria: all guidelines that meet these criteria would then be posted. This would help present and clarify the different guidelines available to practitioners for diagnosing and treating Lyme and tick-borne diseases. A centralized resource library would also help physicians cite sources for their treatment decisions, which in turn would help patients obtain medical insurance coverage for these treatment options.

While the federal government does not endorse any one set of guidelines, there are currently two sets of peer-reviewed guidelines to help guide how doctors treat patients for Lyme disease: the IDSA guidelines (2006) and the ILADS guidelines (2014). Both IDSA and ILADS guidelines are voluntary, yet some medical boards have penalized doctors for treating patients according to the ILADS guidelines. According to patients and caregivers, many insurance companies deny care if patients remain symptomatic after treatment according to the IDSA guidelines. Beyond the guidelines, many Roundtable participants emphasized how the complexities of tick-borne diseases require individualized precision medicine.

## All Hazards Approach

In addition to prevention, diagnosis, and treatment, the Lyme Innovation Roundtable included discussions about an All Hazards approach to Lyme and tick-borne diseases. The All Hazards approach focuses on developing robust data-driven systems that can be used to track, respond to, and recover from virus outbreaks and epidemics and other emerging threats, such as the 2014 Ebola outbreak or the 2015 Zika epidemic. This approach is intended to rapidly deploy resources and information to address and manage public health hazards. The All Hazards infrastructure could be effectively engaged for Lyme and tick-borne diseases because they present a persistent and dynamic threat to public health. In order to make this possible, Roundtable participants discussed several key priorities:

### Develop a data-driven, standardized process to address tick-borne conditions

Roundtable participants recommended developing a shared vocabulary across multiple diseases. This would create a coherent infrastructure designed to disseminate information to the public health community. A universal or standardized "data dictionary" would make it possible to integrate data about multiple public health threats. By developing such a data dictionary, the system could scale to include Lyme and other tick-borne diseases.

### Integrate a tick-borne conditions "use case" into the All Hazards infrastructure integrated with EHR data

Electronic health records (EHRs) provide valuable data on the outbreak and travel of disease epidemics. By developing evaluation tools and recommendations that are both human-readable and machine-readable, EHRs could be easily integrated into the larger infrastructure to notify researchers, health care providers, and policymakers when outbreaks begin. This framework could provide responsive feedback about risk and exposure factors to doctors as they seek to diagnose and treat patients. The integration of a common framework for evaluating hazards into a larger structure would allow researchers and practitioners to link direct clinical care workflow such as occurs in EHRs to biorepositories, large databases that store biological and medical data.

### Develop standardized screening protocols for tick-borne conditions, customized by geographic region

Standardized diagnostic screening protocols should include basic questions that incorporate information about travel history, exposure potential (including whether patients spend substantial time in tick-heavy areas or have pets that may carry ticks), seasonal information, and geographic location. Moreover, doctors should examine relevant symptoms, including triggers such as fever, rashes, and myalgia or arthritis, to improve diagnostic accuracy. By standardizing screening protocols, health care providers and researchers can improve the quality of data that they draw upon as well as input into the All Hazards system and related biorepositories. Roundtable participants recommended piloting the All Hazards use case for tick-borne diseases in one state or region, iterating the approach, and then scaling and customizing by geographic region.

# Actionable Next Steps

The results of the Roundtable suggest several next steps that stakeholders working on Lyme and tick-borne diseases can take in the near term. The proposals presented here do not constitute official or formal policy recommendations but rather a summary of individual views and suggestions from the Roundtable and discussions after the event.

### Leverage public-private collaborations to drive innovation

Given the overarching challenges related to funding, Roundtable participants suggested developing public-private collaborations that would allow for strategic, needs-based allocation of resources for Lyme and tick-borne diseases.

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| Desired Impact | Drive innovation in ways that augment current federal funding and leadership.<br><br>Identify partners in the public and private sectors who will participate. |
| Resources Needed | Secure initial funding, ideally with cost sharing from both private and public sources.<br><br>Establish agreements, procedures, and infrastructure for public-private collaborations. |
| Key Stakeholders | Federal and state agencies, academia, research institutions, patient advocates, health care providers, private sector companies, philanthropic organizations, the general public |
| Opportunities for Collaboration | Building on the experiences of the KidneyX program convened by HHS and the American Society of Nephrology, host a series of prize competitions for Lyme and tick-borne diseases. For example, harness the power of the crowd with a "Design-a-Thon" to crowdsource educational materials (e.g., posters and videos) for Lyme disease prevention.<br><br>Establish a cooperative agreement for tick-borne diseases between BARDA/DARPA, industry, and philanthropic organizations so that future federal dollars are matched 1:1.<br><br>Expand HHS use of Fellows, Intergovernmental Personnel Act (IPA) programs, and other "Tours of Duty" for technologists and problem solvers from industry and academia to join HHS on term-limited assignments to help tackle tick-borne diseases.<br><br>Establish a public-private governance process for data standards, harmonization, and ethics surrounding tick-borne disease information access and interoperability, including cooperative research with patients and through patient registries.<br><br>Support lightweight, agile, data-driven collaborations (e.g, The Opportunity Project (TOP) and TOP Health technology sprint) for industry to create value from government data.<br><br>Co-create a communal roadmap that brings patients, advocates, health care providers, and researchers together to determine priorities for action. |
| Actionable Next Steps | Host a follow-up Lyme Roundtable or Summit to convene diverse stakeholders willing and able to advance public-private collaborations.<br><br>Identify opportunities that would not be possible without collaboration between public and private sector stakeholders, then make the business case for ROI and rationale. |

## Develop a national strategy and coordinating Office of Strategic Initiatives for Tick-Borne Conditions

Lyme and tick-borne diseases are becoming more prevalent throughout the United States. Developing a national strategy to address tick-borne diseases could greatly improve the government's ability to respond, especially if HHS simultaneously created a new Office of Strategic Initiatives for Tick-Borne Conditions with a Director, staff, and resources. The federal government has used this approach successfully with other diseases, such as HIV/AIDS and Ebola.

A national HHS Office of Strategic Initiatives for Tick-Borne Conditions would require interdisciplinary expertise in science, policy, and diplomacy to execute across all HHS Operating Divisions and break down existing silos for improved national coordination and outcomes. Such an office could be created as an extension of the HHS Office of the CTO in the Immediate Office of the Secretary, or perhaps as a BARDA DRIVe (Division of Research, Innovation, and Ventures) program with the Office of the Assistant Secretary for Preparedness Response (ASPR). The Director could report directly to the HHS Secretary with oversight from Congress and the White House.

The HHS Secretary could establish such an office today, potentially modeled after the introduced legislation H.R.220: National Lyme and Tick-Borne Diseases Control and Accountability Act of 2019. It would oversee, develop, and coordinate the national strategy, while shepherding public-private collaborations and opportunities for funding research. Roundtable participants recommended that such an office oversee biorepositories, surveillance data on ticks, and data on tick-borne disease outbreaks, diagnostic results, and general research findings. Establishing such an office would demonstrate to patients, medical providers, academia, industry, and members of the Lyme disease community that HHS and the federal government are responding to their demands and seriously addressing tick-borne diseases.

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| **Desired Impact** | Greatly improve national coordination for funding and support for Lyme research, data collection, and data sharing to enable "deep medicine" and emerging technologies.<br>Improve data sharing between researchers and health care providers to empower new lines of research and potential breakthroughs.<br>Improve trust with the Lyme and tick-borne diseases community by signaling commitment to improved diagnosis and treatment. |
| **Resources Needed** | Appoint a Director for a new HHS Office of Strategic Initiatives for Tick-Borne Conditions.<br>Secure funding to establish, staff, and resource the newly-formed HHS Office. Funding may come from external, non-government sources via a public-private partnership, a cooperative agreement (e.g., HHS, DOD, DOE National Labs, and VA), or solely HHS.<br>Empower the Director with broad HHS authorities, potentially analogous to the BARDA crosscutting approach or the Office of the CTO reporting directly to the HHS Secretary.<br>Provide newly-formed HHS Office with access to all science and existing biorepositories. |
| **Key Stakeholders** | Federal agencies and HHS Operating Divisions like CDC, ASPR/BARDA, NIH, FDA, CMS, and OASH that coordinates the TBDWG; state and local governments; Council of State and Territorial Epidemiologists (CSTE); IDSA, ILADS, and medical practitioners; patients and caregivers; research and academic institutions; philanthropic and non-profit organizations; translational data scientists and bioinformaticians. |

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| **Opportunities for Collaboration** | Strategically work across government and with the many nonprofits, academics, advocates, and private organizations that operate in this space to define the potential roles and responsibilities of this HHS Office.<br><br>Long-term, have this new HHS Office co-create solutions with patients and diverse stakeholders as partners to help guide national strategy, basic research, and policy. |
| **Actionable Next Steps** | Convene a follow-up Lyme Roundtable or Summit on National Strategy, which could be a multi-stakeholder workshop organized by the HHS Office of the CTO and/or the TBDWG.<br><br>Draft a white paper with ROI and business case, detailing the need for such an HHS office and its potential benefits with a strategic plan, timeline, and budget needed for execution.<br><br>In collaboration with diverse stakeholders—including scientists, medical practitioners, policy makers, subject-matter experts and "Lyme Ambassadors" from the Lyme disease community—identify and articulate priority problems that require federal action now. |

## Implement better vector control techniques and improve surveillance data

In addition to disseminating information about Lyme and tick-borne diseases, federal resources can be put into developing and implementing vector control techniques that can be applied to personal lawns and in public and national parks. Controlling vectors such as black-legged ticks can reduce the prevalence of Lyme and other tick-borne disease infections. The process of improving vector control will provide important opportunities to conduct surveillance and contribute to publicly available databases that store geospatial and temporal information on tick prevalence.

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| **Desired Impact** | Reduce the number of infections of Lyme and tick-borne diseases.<br><br>Improve publicly available data on tick surveillance. |
| **Resources Needed** | Secure funding and access to technologies for deploying repellents. |
| | Develop a public-facing database that provides real-time updated information about tick prevalence and allows users to verify and upload surveillance data. |
| | Develop one or more applications (either websites or mobile apps) that allow doctors, patients, parks departments and homeowners to provide updated information about tick sightings, the application of vector control products, and confirmed infections. |
| **Key Stakeholders** | National and public parks, government departments, Army Public Health Center, school districts, industry leaders |
| **Opportunities for Collaboration** | Develop collaborations between state/local health departments. |
| **Actionable Next Steps** | Develop a campaign to educate homeowners about creating “tick-safe” zones using simple landscaping and EPA-approved pesticides.<br><br>Conduct research to identify targets and/or pathways for the continued development of repellents and insecticide products. |

## Gather data from Lyme and tick-borne disease patients to develop our understanding of these diseases

Many Roundtable participants who had been infected with Lyme disease expressed their frustration with traditional relationships between health care providers and patients. Several had suffered from missed or delayed diagnosis due to insensitive diagnostic tests and/or overly strict criteria for diagnosing Lyme disease. Many were dismayed by physicians' reluctance to use off-label treatment options, which patients found necessary to reverse severe, disabling symptoms. Many doctors who did treat off-label did not take insurance, so treatment for Lyme disease was often prohibitively expensive.

Roundtable participants suggested addressing these issues, in part, by providing patients with the option to voluntarily share biological data with qualified researchers and health care providers. Additional sources of patient data could give doctors access to new case studies that could allow them to better treat patients whose symptoms do not fit within established CDC case definitions, or whose symptoms are so severe that they cannot be alleviated with conventional treatments. This data could also help connect patients with available clinical trials and experimental therapies for tick-borne diseases.

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| **Desired Impact** | Build trust between patients, health care providers, and researchers by making it easier for patients with Lyme disease to be diagnosed accurately at all stages of the disease, which will help align patient experiences with clinical practice and basic science research.<br><br>Empower patients to work with their doctors to assess all treatment options with informed consent, customized to their individual risk tolerances and situation.<br><br>Provide funding for the storage and management of patient-generated data. |
| **Resources Needed** | Make strategic investments in data infrastructure — including data governance and data ethics — to support quality, interoperable data (beyond Blue Button 2.0) for complex tick-borne conditions. |
| **Key Stakeholders** | HHS agencies including CDC, CMS, NIH, and FDA; patients and patient advocacy organizations, health care providers, MyLymeData, ClinicalTrials.gov, academic and clinical research institutions, cloud service providers, and others |
| **Opportunities for Collaboration** | Build on the power of existing initiatives like the MyLymeData registry, which enables Lyme patients to submit their own data.<br><br>Integrate patient data with ClinicalTrials.gov matching tools to help connect patients with available clinical trials related to Lyme and tick-borne diseases.<br><br>Identify partners inside and outside government that would be interested in hosting, contributing to, and/or analyzing patient data. |
| **Actionable Next Steps** | Have the HHS Office of the CTO consider running a pilot project in data-driven trust-building by connecting data scientists with existing resources and registries (e.g., MyLymeData, NIH's All of Us, VA's Million Veteran Program) to explore how translational data science may yield insights and understanding across diverse stakeholders for tick-borne diseases. |

## Facilitate access to updated guidelines on diagnosis and treatment

Roundtable participants suggested that one of the best ways to improve diagnosis and treatment of Lyme disease would be to improve the way in which guidelines are made available to the public and health care providers. The lapse of funding in 2018 for the National Guideline Clearinghouse (NGC) has hindered the ability of doctors to access and critically consider the full range of guideline options for diagnosing and treating Lyme disease. Many participants supported HHS reinstatement of the NGC with funding from the Agency for Healthcare Research and Quality (AHRQ) to provide open access to the most up-to-date, peer-reviewed guidelines across organizations. If HHS funding remains unavailable, then Roundtable participants encouraged HHS to transition the NGC to a neutral, third-party provider that would curate all guidelines that satisfied clearly defined inclusion criteria.

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| **Desired Impact** | Make it easier for patients, doctors, and medical boards to access up-to-date guidelines on diagnosis and treatment.<br><br>Improve patient outcomes and build trust within the field of Lyme and other tick-borne diseases by empowering patients and doctors to exercise judgment on a case-by-case basis in selecting courses of medical treatment. |
| **Resources Needed** | Request support from NIH or other HHS Operating Division(s) to reactivate and maintain the NGC on the AHRQ website.<br><br>If HHS/AHRQ will not host the NGC, identify opportunities for Congressional funding.<br><br>If Congress and federal government will not fund the NGC, identify external resources to maintain the NGC (or its equivalent) on a third-party website. |
| **Key Stakeholders** | HHS, including AHRQ, CDC, NIH; IDSA, ILADS, health care providers, insurance companies, clinical labs, patients |
| **Opportunities for Collaboration** | Public and private sector organizations — including HHS, IDSA, and/or ILADS — could collaborate to provide resources for the reinstatement of the NGC (or its equivalent). |
| **Actionable Next Steps** | During the interim period (until the NGC, or its equivalent, is reinstated), have the TBDWG publish a neutral .gov (static) webpage with basic information and links to both the IDSA and ILADS clinical practice guidelines for Lyme disease.<br><br>Evaluate the funding needs associated with reinstating the NGC, including whether HHS/AHRQ can host the platform as an independent clearinghouse.<br><br>Reach out to medical licensing boards to ensure that practitioners are aware of these updates and can access these guidelines for diagnosis and treatment. |

## Advance the scientific understanding of Lyme disease with federally funded R&D

In order to advance the scientific understanding of Lyme disease, HHS and the Lyme disease community must develop clear incentives for researchers and labs to tackle critical research questions. An important long-term goal is to develop a "gold standard" diagnostic test and definition of Lyme disease that would serve as a universal point of reference (Marques, 2015). A gold standard diagnostic, which could isolate and culture the Lyme-causing bacteria in patients with active infection, would improve case definitions, help evaluate treatment effectiveness, and advance research on pathogens and the vectors that carry them. Many Roundtable participants believe that improving diagnostic tests could be the most high-impact result of federally funded research in this field. Ultimately, improved Lyme disease diagnostic tests would lead to more timely diagnosis, more targeted treatments, and improved patient outcomes.

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| **Desired Impact** | Develop a "gold standard" diagnostic test with ability to isolate and culture *B. burgdorferi* from any patient with active infection, no matter the disease stage or manifestations.<br><br>Use the (future) gold standard as the underlying basis of a new definition for Lyme disease, which would address today's nomenclature challenges with government, researchers, clinicians, and patients all using different terms and different definitions. |
| **Resources Needed** | Increase the NIH budget for tick-borne disease research since significant R&D is required.<br><br>Leverage resources across HHS (beyond only NIH), from other federal agencies such as the DOD Defense Advanced Research Projects Agency (DARPA), DOE National Labs, and the VA, and from external foundations for medical research. |
| **Key Stakeholders** | Federal agencies, especially NIH, and researchers, health care providers, and funders |
| **Opportunities for Collaboration** | Bring together experts inside and outside of government to proactively revise prior assumptions about Lyme and tick-borne disease. |
| **Actionable Next Steps** | Explore the World Health Organization's One Health ecosystem-driven solutions program, including understanding tick biology and life history.<br><br>Augment existing HHS and NIH grants-review processes with methodologies from the Congressionally Directed Medical Research Programs (CDMRP), which includes patients and diverse stakeholders in the grant review process to select federally funded R&D.<br><br>Host regional "Tick-Borne Disease Catalyzing Science Summits" with researchers, industry, philanthropists, and others to discuss the state of the science and funding opportunities to advance R&D priorities.<br><br>Have the HHS Office of the CTO and external partner(s) co-lead an X-PRIZE for Lyme diagnostics. |

## Create and pilot the All Hazards "use case" for Lyme and tick-borne diseases

The All Hazards table prototyped how to clinically manage the complex challenges surrounding Lyme and tick-borne diseases. One challenge is "translating" all of the many disease complexities into a clear, standardized process integrated with EHRs. Roundtable participants worked to define key words and concepts, beginning with acute Lyme disease, which are a requirement for disseminating information to public health communities.

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| Desired Impact | Translate the best available science into clinical guidance and standardize diagnostic screening tools that are integrated into EHRs for Lyme disease.<br><br>Extend the All Hazards "use case" of Lyme disease to include all tick-borne diseases and conditions, customized by geographic location.<br><br>Develop the All Hazards infrastructure so that it supports two-way information exchange, including automated reporting for confirmed and suspected cases of tick-borne diseases. |
| Resources Needed | CDC and the HHS Office of the National Coordinator for Health Information (ONC) have funded efforts to develop a Lyme disease component to the All Hazards framework, and should continue to do so.<br><br>Piloting this framework will require additional funds, as well as a state partner that is willing to work with HHS Office of the CTO to rapidly test and iterate. |
| Key Stakeholders | HHS Immediate Office of the Secretary (IOS), CDC, ONC; CSTE, local, and state public health experts; health care providers |
| Opportunities for Collaboration | Bring together experts inside and outside of government to revise prior assumptions by updating EHR users with current information on Lyme and tick-borne diseases, including what diagnostic tests to order by region and best practices when interpreting test results.<br><br>HHS Office of the CTO will identify potential state partner(s) in high-endemic areas, e.g.:<br><br>Massachusetts Department of Public Health<br><br>Maine Office of Innovation and the Future<br><br>Civic Digital Fellows 2019 will help design and build the pilot use case. |
| Actionable Next Steps | HHS Office of the CTO will identify state partner(s) and co-lead a workshop/webinar or series of workshops/webinars to roll out the pilot in the test state(s), solicit feedback, iterate, and incrementally build out the All Hazards use case for Lyme disease in New England. |

# Conclusion

For the first time in HHS history, the 2018 Lyme Innovation Roundtable brought together experts from government, industry, academia, clinical research institutions, patient advocacy groups, nonprofits, and philanthropic organizations to harness the power of collaboration, data-driven innovation, and emerging technologies for Lyme and tick-borne diseases. More than 80 Roundtable participants discussed and provided their input on prevention, diagnosis, and treatment, and the All Hazards approach.

This Roundtable was part of a larger Lyme disease initiative from the HHS Office of the CTO and can serve as a model for further work. In holding the Roundtable, HHS recognized the importance of stakeholder engagement in fighting Lyme and tick-borne diseases. As with many complex problems, solutions will have to come by engaging people, processes, and technology, in that order. The Roundtable demonstrated the value of gathering diverse perspectives from individual stakeholders to help prioritize goals, understand needs, and identify opportunities for combating tick-borne diseases.

One recurring theme from the day was the importance of trust, and how trust is essential to enable transformative technologies and scientific research to move forward. Individuals spoke about the importance of improving government transparency and access to information, including access to data and biorepositories. Researchers share data and information among themselves with standards for quality and interoperability, yet many patients are denied access to their own laboratory results and information from biospecimens they have donated. Many participants raised the issue of data ethics and how to enhance trust through ethical use of data in science.

Participants asked for more "big tent" stakeholder discussions, like this Roundtable, to bring together all kinds of individuals and organizations concerned with Lyme and tick-borne diseases. They recognized the need to involve researchers, healthcare providers, and patients themselves, including organizations from government, the private sector, and the nonprofit community. An ongoing, multi-stakeholder approach that mirrors the diversity of this Roundtable will, over time, help to build understanding and strengthen trust.

HHS will need to lead, coordinate, and oversee the national strategy for tick-borne diseases. Participants identified a range of priorities with strong recommendations, including that HHS:

- Leverage public-private collaborations to drive innovation.
- Develop an integrated national strategy with coordinated federal response to tick-borne diseases.
- Establish a new HHS office — for example, an Office of Strategic Initiatives for Tick-Borne Conditions — with a "Lyme Czar" Director to execute the national strategy.
- Implement better vector control techniques and improve surveillance data.
- Gather data from Lyme and tick-borne disease patients to augment conventional research with crowdsourced data (e.g., TickTracker app), patient registries (e.g., MyLymeData), and emerging technologies (e.g., AI with wearables).
- Facilitate open access to information, especially clinical guidelines on diagnosis and treatment.
- Fund R&D to advance the scientific understanding of Lyme disease with priority on developing a gold standard diagnostic test (i.e., error-free classification).
- Create and pilot the All Hazards "use case" for Lyme and tick-borne diseases.

This Roundtable, and the research and discussions that have followed in preparing this report, have shown how new digital approaches to medical diagnosis and treatment will help address Lyme disease and tick-borne conditions. Shared, interoperable data and emerging technologies enable new insights for prevention, diagnosis, treatment, and patient outcomes. The large-scale analysis of EHRs, as Geisinger is now doing in its collaboration with Johns Hopkins University, can help identify problems in diagnosis and treatment as well as factors that contribute to clinical success. Using biobanks and new analytic capacities for medical

data, today's research analyzes large numbers of blood and tissue samples to help develop biological markers for Lyme disease — a critical step for both research and patient care.

Throughout the Lyme Innovation Roundtable, the White House participants and HHS leadership reaffirmed their commitment to emerging technologies and data-driven innovations for Lyme and tick-borne diseases. Developing sciences like AI have enormous potential to revolutionize data insights for clinical use. Since the Roundtable, the Executive Order on Maintaining American Leadership in Artificial Intelligence (February 2019) directed federal agencies including HHS to prioritize AI and emerging technologies. This includes providing and using high-quality data needed to drive AI. For example, research related to the All Hazards framework shows how a digital approach to clinical guidelines can help address serious infectious diseases such as Lyme disease. This new approach begins with conventional narrative guidelines and develops them into clinical decision support (CDS) tools that health care providers can use together with EHRs for patient treatment (Michaels and Pacchiana, 2019).

Future progress will rely on working together "with patients as partners," traversing conventional boundaries and crossing disciplines to identify patterns and insights from high-quality data. Patient-practitioner partnerships and emerging methodologies in "deep medicine" (Topol, 2019) should usher in a new generation of diagnostics, treatments, and solutions for Lyme and tick-borne diseases.

There is a clear opportunity for an aggressive, data-driven initiative for Lyme and tick-borne diseases to advance patient-centered, value-based healthcare with emerging technologies. As a global leader in technology and innovation, the United States can develop a coordinated national strategy to contain and cure Lyme and tick-borne diseases.

Many participants recommended that this strategy be developed and led by a new coordinating office in HHS, which could be called the Office of Strategic Initiatives for Tick-Borne Conditions. This Office could be an extension of the Lyme Innovation initiative led by the HHS Office of the CTO in the Office of the Secretary, or part of BARDA as an extension of the DRIVe innovation efforts including public-private partnerships. Irrespective of its office location and federal reporting structure, the Office will require broad authority to work across all of HHS to develop a strategy to cover all 50 states. The Office and its Director should be empowered to holistically address tick-borne conditions with a value-based, patient-centered government response across CDC, CMS, FDA, NIH, and all Operating Divisions within HHS.

Conquering Lyme disease and tick-borne conditions will demand significant federal R&D funding and a leadership commitment over many years, analogous to a "Manhattan Project" to combat Lyme disease (Stricker and Johnson, 2014). Roundtable participants stressed that the U.S. Congress should increase budget and appropriations for tick-borne diseases across HHS, DOD, DOE National Labs, VA, and other agencies. To augment federal budgets, participants identified external sources from industry and philanthropy, for example, by launching a LymeX Innovation Accelerator similar to the KidneyX public-private partnership.

The bipartisan Congressional Lyme Disease Caucus gives some hope that Congress may act soon. Recently the Caucus, led by Representative Chris Smith (R-NJ), introduced legislation H.R.220: National Lyme and Tick-Borne Diseases Control and Accountability Act of 2019 to mandate that HHS establish an oversight office and lead a coordinated national strategy. Growing concern over Lyme and tick-borne diseases crosses political lines. As one Roundtable participant said, "Ticks don't care if you're Republican or Democrat."

Addressing these complex illnesses will require a new level of collaboration, coordination, and trust between researchers, physicians, patients, and others who have a stake in seeing tick-borne diseases effectively treated and eventually eradicated. The Lyme Innovation Roundtable was a first step in moving towards a new and promising collaborative model for research, prevention, diagnosis, and treatment.

**The Lyme Innovation Roundtable was supported by**

Located in the Immediate Office of the Secretary, the Office of the Chief Technology Officer (CTO) seeks to instill a culture of innovation at the U.S. Department of Health and Human Services (HHS) through building innovative partnerships, harnessing the power of data and empowering HHS staff with the skills and tools to support a nimble government entity.

The Steven & Alexandra Cohen Foundation was launched in 2001, and is committed to inspiring philanthropy and community service—with a special interest in children's health, education, veterans and the arts—by creating awareness, offering guidance and leading by example to show the world what giving can do.

The Bay Area Lyme Foundation is dedicated to making Lyme disease easy to diagnose and simple to cure. Its focus is on education and the development of better diagnostics and treatments. The Bay Area Lyme Foundation leverages the entrepreneurial spirit of the Bay Area to catalyze new and innovative projects around the country via a combination of direct funding to dedicated Lyme projects, rigorous screening and accountability, providing tools and resources to connect leaders, and improving community outreach.

Ensemble provides technology, marketing, and managed services that combine new ways of working with the most effective industry practices. Ensemble creates impact resonance for organizations through collaboration and user-centered thinking.

The Center for Open Data Enterprise (CODE) is a 501(c)3 nonprofit organization based in Washington, DC. Its mission is to maximize the value of open government data as a public resource for economic growth, social good, and scientific research. Over the past several years, CODE has worked with numerous federal agencies to help them improve how they collect, publish, and apply data to better meet the needs of data users.

# Appendix 1: List of Acronyms and Abbreviations

| | |
|---|---|
| AHRQ | Agency for Healthcare Research and Quality |
| AI | Artificial Intelligence |
| ASPR | Office of the Assistant Secretary for Preparedness Response |
| BARDA | Biomedical Advanced Research and Development Authority |
| CDC | Centers for Disease Control and Prevention |
| CDMRP | Congressionally Directed Medical Research Program |
| CDS | Clinical Decision Support |
| CLIA | Clinical Laboratory Improvement Amendments |
| CMS | Centers for Medicare and Medicaid Services |
| CODE | Center for Open Data Enterprise |
| COE | Center of Excellence |
| CTO | Chief Technology Officer |
| CTSE | Council of State and Territorial Epidemiologists |
| DARPA | Defense Advanced Research Projects Agency |
| DOD | U.S. Department of Defense |
| DOE | U.S. Department of Energy |
| DRIVe | Division of Research, Innovation, and Ventures |
| EHR | Electronic Health Record |
| ELISA | Enzyme-Linked Immunosorbent Assay |
| EM | *Erythema migrans* |
| EPA | U.S. Environmental Protection Agency |
| FACA | Federal Advisory Committee Act |
| FDA | U.S. Food and Drug Administration |
| GAMRIF | Global Antimicrobial Resistance Innovation Fund |
| HHS | U.S. Department of Health & Human Services |
| HPCC | High Performance Computer Cluster |
| IDSA | Infectious Diseases Society of America |
| ILADS | International Lyme and Associated Diseases Society |
| IOS | Immediate Office of the Secretary |
| IPA | Intergovernmental Personnel Act |
| LDB | Lyme Disease Biobank |
| MIDAS | Models of Infectious Disease Agent Study |
| NCATS | National Center for Advancing Translational Sciences |
| NDRI | National Disease Research Interchange |
| NGC | National Guideline Clearinghouse |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIH | National Institutes of Health |
| OASH | Office of the Assistant Secretary for Health |
| ONC | Office of the National Coordinator of Health Information |
| PSA | Public Service Announcement |
| PTLDS | Post-treatment Lyme disease syndrome |
| SFTS | Severe Fever with Thrombocytopenia Syndrome |
| TBDWG | Tick-Borne Disease Working Group |
| TOP | The Opportunity Project |
| VA | U.S. Department of Veterans Affairs |
| WB | Western Blot |

# Appendix 2: Roundtable Agenda

***Purpose:*** *Harness the power of collaboration, data-driven innovation, and emerging technologies for Lyme and tick-borne diseases.*

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| **8:15 AM** | **Registration, Networking & Refreshments** |
| **9:00 AM** | **Welcome**<br>Ed Simcox, Chief Technology Officer, U.S. Department of Health and Human Services (HHS) |
| **9:10 AM** | **Opening Remarks: Patient-Focused Innovation as the Next Frontier for Healthcare**<br>Adam Boehler, Director and Deputy Administrator for Innovation and Quality, Centers for Medicare & Medicaid Services, HHS |
| **9:25 AM** | **Begin with Why — Shared Goals: What Are We Solving For?**<br>Kristen Honey, Innovator in Residence, HHS |
| **9:30 AM** | **Roundtable Participant Introductions** |
| **9:45 AM** | **Opening Keynote: Advancing Science and Partnerships for Patient-Centered Care**<br>Eric Hargan, Deputy Secretary, HHS |
| **10:00 AM** | **Invited Speakers: The Future of Medicine**<br>**Next-Generation Technologies for Prevention, Therapeutics, and Diagnostics**<br>George Church, Founding Core Faculty and Lead, Synthetic Biology, Wyss Institute for Biologically Inspired Engineering, Harvard University<br>**How Clinical Data Capture is Changing Treatment Paradigms**<br>Andy Kogelnik, Director, Open Medicine Institute<br>**Patient-Powered Research: How Can Patient Registry Data Augment Traditional Methods?**<br>Lorraine Johnson (video), Chief Executive Officer, LymeDisease.org |
| **10:30 AM** | **Networking Break** |
| **10:50 AM** | **Breakout Session 1: Identifying Tools & Resources — All Hands on Deck!** |
| **12:00 PM** | **Lunch Break** |
| **1:00 PM** | **Afternoon Welcome and LymeX Public-Private Partnership Co-Creation**<br>Bennett Nemser, Senior Program Officer, Steven & Alexandra Cohen Foundation<br>Kristen Honey, Innovator in Residence, HHS |
| **1:15 PM** | **Coordinated Strategy and Collaborations for Tick-Borne Diseases**<br>Robert Redfield (video), Director, Centers for Disease Control and Prevention (CDC), HHS |

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|---|---|
| **1:30 PM** | **Lightning Talks: The Art of the Possible Today**<br><br>**The Next Frontier: Addressing the 1% Problem**<br>Wendy Adams, Research Grant Director, Bay Area Lyme Foundation<br><br>**Expanding the Solution Space: Examining the Other Trees in the Forest**<br>Robert Mozayeni, Founder and Executive Director, Translational Medicine Group<br><br>**Incorporating New Data and Exapting Insights from Other Diseases: A View from Academic Medicine**<br>Linden Hu, Vice Dean for Research, Tufts University School of Medicine<br><br>**Prevention: The Next-Generation of Solutions**<br>Ben Beard, Deputy Director, Division of Vector-Borne Diseases, CDC, HHS<br><br>**Data in Action: Lessons from the Cancer Genome Atlas Project**<br>Theo Knijnenburg, Senior Research Scientist, Institute for Systems Biology |
| **2:00 PM** | **Breakout Session 2: Collaboration and Partnerships for LymeX Success** |
| **2:50 PM** | **Networking Break** |
| **3:10 PM** | **Breakout Session 3: LymeX Proposals for Real-World Impact** |
| **4:00 PM** | **Presentation of Highlights to Government Leadership and VIPs**<br>*Each breakout table will share their response to the following question:*<br><br>*"If you had three minutes with the HHS Secretary, what near-term actions would you propose to transform the landscape of tick-borne disease prevention, diagnosis, and treatment?"* |
| **4:50 PM** | **Leading By Example to Catalyze Collaborative Solutions**<br>Bennett Nemser, Senior Program Officer, Steven and Alexandra Cohen Foundation |
| **5:00 PM** | **Closing Keynote: The "All of Us" Research Program and PPPs for a New Era in Health**<br>Francis Collins*, Director, National Institutes of Health, HHS |
| **5:15 PM** | **Adjourn for Networking Reception** |

*The **Lyme Innovation Roundtable** is an invitation-only event designed to elicit individual views and suggestions from experts in the field. Participants will join the Roundtable for a one-time event, not as a regular group, and are not expected to reach consensus on topics of discussion. All input will be taken as suggestions for a public report rather than as formal recommendations.*

***To ensure openness of discussion, the Roundtable will be held under the Chatham House Rule:***
*Any participant is free to use information from the day but is not allowed to reveal who made any comment. All participants are invited to attend a Networking Reception immediately after the Roundtable.*

# Appendix 3: Participating Organizations

## Academic and Clinical Research

**Boston Children's Hospital** is a comprehensive center for pediatric healthcare. As one of the largest pediatric medical centers in the United States, Children's offers a complete range of healthcare services for children from birth through 21 years of age.

**Ceres Nanosciences** is engaged in the research, development, and commercialization of innovative sample preparation products and diagnostic tests, based on its proprietary Nanotrap® particle platform. The versatility and performance of the Nanotrap® technology allows Ceres to partner across the life sciences, pharma, and clinical diagnostics space, resulting in improved patient outcomes and reduced health care costs.

**Cognitive Medical Systems** works to empower people to make informed health decisions through the use of innovative software. Their needs for evidence-based healthcare and reducing the variance in healthcare delivery are what drive us to build standards-based Clinical Decision Support (CDS) systems that simplify complex workflows and help save valuable time.

**FasterCures**, a center of the Milken Institute, is a nonprofit organization that works to improve the medical research system and make it faster. Its mission is to save time in the way new therapies get from discovery to patients.

**Harvard University, *Wyss Institute for Biologically Inspired Engineering*** uses biological design principles to develop new engineering innovations that will transform medicine and create a more sustainable world.

**IGeneX** is a global leader in the research and development of tests that accurately detect Lyme disease, Relapsing Fever, and other tick-borne diseases. IGeneX makes it their singular mission to offer best-in-class testing for tick-borne diseases that delivers the most comprehensive and accurate results possible.

**Institute for Systems Biology** is a nonprofit biomedical research organization based in Seattle. ISB serves as the ultimate environment where scientific collaboration stretches across disciplines and across academic and industrial organizations, where their researchers have the intellectual freedom to challenge the status quo.

**Internal Medicine of Northern Virginia** is a specialty care practice that focuses on the management of chronic Lyme disease, Fibromyalgia and chronic fatigue. We also treat Primary Care concerns. They also provide services such as IV Vitamin C, IV Glutathione, IV Myers and hyperbaric oxygen therapy ensuring that each patient has an individualized protocol.

**Johns Hopkins Medicine** is a governing structure for the University's School of Medicine and the health system, coordinating their research, teaching, patient care, and related enterprises.

> **Johns Hopkins Bloomberg School of Public Health** is dedicated to the education of a diverse group of research scientists and public health professionals, a process inseparably linked to the discovery and application of new knowledge, and through these activities, to the improvement of health and prevention of disease and disability around the world.

**Open Medicine Institute** is a research and service organization bridging the gaps in healthcare through targeted use of information and biotechnology. OMI runs clinical trials, community-based research programs, health improvement programs and has core lab services that enable patients, physicians and researchers.

**ProgeneDX** is a contract research organization dedicated to the study of chronic, inflammatory disease (CIRS) and other related inflammatory diseases. Their goal is to bring health to people suffering from diseases related to chronic inflammation. They are a Delaware company and serve healthcare practitioners across the United States.

**Smartlink Health** has a mission to break down healthcare's communication silos and help their colleagues more easily bridge the gap between fee-for-service and value-based payments. Smartlink is focused on developing smart, disruptive solutions that improve health outcomes, drive new revenue streams, and enable better efficiency.

**State University of New York Adirondack** has one of the largest, most comprehensive university-connected research foundation in the country and a multitude of influential centers and institutes, SUNY helps power New York State's economy while making an impact across the globe.

**Translational Medicine Group** is a unique medical practice, where world class training, experience and knowledge of medical science and medical informatics are tempered with compassion and evidence-based medicine to provide effective personalized medical solutions.

**Tufts University School of Medicine** has a mission to educate a diverse body of students and advance medical knowledge in a dynamic and collaborative environment. We seek to foster the development of dedicated clinicians, scientists, public health professionals, and educators who will have a sustained positive impact on the health of individuals, communities, and the world.

**University of Maryland, *School of Public Health*** strives to promote and protect the health and well-being of the diverse communities throughout Maryland, the nation, and the world through leadership and collaboration in interdisciplinary education, research, practice, and public policy.

**U.S. Biologic** works to reduce zoonotic disease by combining One Health solutions with predictive analytics. These solutions can be of invaluable use to professionals who work to reduce disease such as pest-management professionals, public health officials, and veterinarians.

**Virginia Commonwealth University, *School of Medicine*** has a mission is to provide preeminent education to physicians and scientists in order to improve the quality of healthcare for humanity. Through innovative, scholarly activity and a diverse educational context, the School seeks to create and apply new knowledge, and to provide and continuously improve systems of medical and science education.

## Industry, Nonprofits, and Philanthropy

**Bay Area Lyme Foundation's** mission is to put a stop to Lyme disease. Its focus is on prevention and the development of better diagnostics and treatments.

The **Center for Open Data Enterprise** is an independent nonprofit organization that works to maximize the value of open government data for economic growth, social good, and scientific research.

**Clyme Health** is dedicated to improving the lives of people living with Lyme disease and other invisible illnesses. Clyme Health works to capture each person's unique diagnostic and treatment experience, surface insights, and share results to improve treatment for individuals and the collective whole.

**Ensemble** provides technology, marketing, and managed services that combine new ways of working with the most effective industry practices. Ensemble creates impact resonance for organizations through collaboration and user-centered thinking.

**Falcon Edge Capital** is an employee-owned hedge fund sponsor. The firm primarily provides its services to pooled investment vehicles and invests in the public equity markets across the globe with a focus on global emerging markets.

**Geisinger** is a coordinated intersection of services and providers – primary care and specialists, hospitals and trauma centers, insurance, medical education and research. Geisinger has expanded and evolved to meet regional needs and developed innovative, national programs in the process.

**Global Lyme Alliance** is the leading 501 (c)(3) dedicated to conquering Lyme and other tick-borne diseases through research, education and awareness. GLA has gained national prominence for funding the most urgent and promising research in the field, while expanding education and awareness programs for the general public and physicians.

**GuideStar** connects donors and grantmakers to non-profit organizations and fund medical research. GuideStar believes that in-depth and comparable data about organizations can create real change within the nonprofit sector. They encourage all nonprofit organizations to get involved.

**Hudson Valley Healing Arts Center** takes a holistic approach to health, and specialize in treating tick-borne diseases. They incorporate traditional and integrative therapies into a comprehensive treatment plan to help you regain your health.

**International Lyme and Associated Diseases Society** (ILADS) is a nonprofit, international, multidisciplinary medical society dedicated to the appropriate diagnosis and treatment of Lyme and associated diseases.

**Kaiser Permanente** is one of the nation's largest not-for-profit health plans, serving 12.2 million members. It comprises Kaiser Foundation Hospitals and its subsidiaries, Kaiser Foundation Health Plan, and the Permanente Medical Groups.

**LabCorp** is a leading global life sciences company that is deeply integrated in guiding patient care, providing comprehensive clinical laboratory and end-to-end drug development services. With a mission to improve health and improve lives, LabCorp delivers world-class diagnostic solutions, brings innovative medicines to patients faster and uses technology to improve the delivery of care.

**LivLyme Foundation** has a mission is to raise money for children whose families cannot afford the necessary medication or treatment for Lyme disease. They will also provide grants and support the medical community until a cure is found. LivLyme Foundation will promote education and awareness about Lyme and the associated diseases.

**TickTracker** is an app that helps users report and track ticks in real time. TickTracker is a program of the LivLyme Foundation.

The **Lyme Disease Association** (LDA) is a 501(c)(3) nonprofit whose mission is promoting awareness of and controlling the spread of Lyme and other tick-borne diseases (TBD) and their complications through education and other means; raising and distributing funds for Lyme and tick-borne diseases (TBD) research, education and other related Lyme and TBD issues; assisting underprivileged patients in connection with Lyme and other TBD.

LymeDisease.org is a nonprofit 501(c)(3) that serves the patient community through advocacy, education and research.

The **MITRE Corporation** is working to solve some of the nation's biggest challenges in defense, cybersecurity, healthcare, homeland security and the judiciary. MITRE is a systems engineering company committed to the public interest, operating federally funded R&D centers on behalf of U.S. government sponsors. MITRE's

mission-driven teams are dedicated to solving problems for a safer world.

The **Steven & Alexandra Cohen Foundation** is committed to inspiring philanthropy and community service—with a special interest in children's health, education, veterans and the arts—by creating awareness, offering guidance and leading by example to show the world what giving can do.

**TellMed Strategies** is a group of communicators with a passion for health and health sciences. We aim to elevate the perception of companies and organizations that are doing valuable research and providing important medical solutions, and we work to raise awareness for important health/medical issues.

## Government Agencies and Offices

The **U.S. Department of Defense** (DOD) is responsible for providing the military forces needed to deter war and protect the security of our country.

The **U.S. Army Public Health Center's** mission is to enhance Army readiness by identifying and assessing current and emerging health threats, developing and communicating public health solutions, and assuring the quality and effectiveness of the Army's Public Health Enterprise.

The **Armed Forces Pest Management Board's** (AFPMB) mission is to ensure that environmentally sound and effective programs are present to prevent pests and disease vectors from adversely affecting DoD operations.

The **Congressionally Directed Medical Research Programs** (CDMRP) is a global funding organization located within the Department of Defense that fosters high impact, high risk and high gain research projects that respond to the needs of its stakeholders, including the American public, the military, and Congress.

The **Tick-Borne Disease Research Program** (TBDRP) is an initiative within the Congressionally Directed Medical Research Programs that was designed to support innovative and impactful research that addresses fundamental issues and gaps within the field of tick-borne disease.

The **U.S. Department of Health and Human Services** is a cabinet-level department of the U.S. federal government with the goal of protecting the health of all Americans and providing essential human services.

The **Agency for Healthcare Research and Quality** (AHRQ) mission is to produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

The **Biomedical Advanced Research and Development Authority** (BARDA) mission is to develop and procure needed medical countermeasures, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin.

The **Centers for Disease Control and Prevention Center** (CDC) works to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

The **Division for Vector-Borne Diseases** is a national and international leader in researching, preventing, and controlling viruses and bacteria spread by vectors like mosquitoes, ticks, and fleas. Their staff includes entomologists, epidemiologists, molecular biologists, laboratorians, microbiologists, physicians, veterinarians, virologists, and zoologists.

The **Centers for Medicare and Medicaid Services** (CMS) mission is to ensure that the voices and needs of the populations we represent are present as the agency is developing, implementing, and evaluating its programs and policies.

The **Food and Drug Administration** (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

The **Immediate Office of the Secretary** (IOS) is responsible for operations and coordination of the work of the Secretary.

The **Office of the Chief Technology Officer** (CTO) provides leadership and direction on data, technology, innovation and strategy across the U.S. Department of Health and Human Services. Areas of focus include promoting open data and its use to create value, driving more efficient operations through technology utilization, and coordinating innovation strategy across the Department to improve the lives of the American people and the performance of the Department.

The **National Institutes of Health's** (NIH) mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

The **National Cancer Institute** (NCI) is the federal government's principal agency for cancer research and training. NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

The **National Institute of Allergy and Infectious Diseases'** (NIAID) mission is to lead research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

The **Office of the Assistant Secretary for Health** (OASH) oversees 12 core public health office s- including the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps - as well as 10 regional health offices across the nation and 10 presidential and secretarial advisory committees.

The **U.S. Department of Veterans Affairs** (VA) mission is to fulfill the promise of President Lincoln to the Veterans of the United States armed services, which is to provide Healthcare to those who have served, and to their families.

The **Virginia Department of Health** mission is to protect the health and promote the well-being of all people in Virginia.

The **White House Office of Management and Budget's** mission is to serve the President of the United States in implementing his vision across the Executive Branch.

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