

CODE

LymeX Roundtable: Bridging the Trust Gap

SUMMARY REPORT
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Executive Summary

Lyme disease is the most common vector-borne disease in the United States, with approximately 476,000 Americans diagnosed and treated each year. In April 2021, The U.S. Department of Health and Human Services (HHS), the Steven & Alexandra Cohen Foundation, and the nonprofit **Center for Open Data Enterprise** (CODE) co-hosted a *LymeX Roundtable: Bridging the Trust Gap* to collaborate on inclusive strategies for patient-driven research and patient-driven innovation. The Roundtable was part of the **LymeX Innovation Accelerator (LymeX)**, a public-private partnership between HHS and the Steven & Alexandra Cohen Foundation. After a public webinar, almost 70 invited participants, including patients, doctors, researchers, and policymakers, participated in two breakout sessions designed to develop new, trust-building, inclusive approaches to improve patient outcomes for Lyme disease: *Patient-Driven Innovation* and *Patient-Driven Data for Research*.

The Patient-Driven Innovation track produced new insights and ideas for a range of innovative opportunities that can help individuals with Lyme disease and the public. Roundtable participants discussed *digital tools* to track ticks, identify Lyme infection, and track and report symptoms. They suggested ways that improve *surveillance information* to understand the spread of Lyme disease better. They discussed the need for better *education* around Lyme for clinicians and the public, and they highlighted the need for improving *connection, convening, and coordination* among all stakeholders.

The breakout sessions on Patient-Driven Data for Research emphasized the importance of engaging patients with respect and understanding in the research process. At the same time, participants described several challenges to making future collaboration a reality, including cultural challenges, data challenges, and issues of trust, ethics, and privacy. They suggested ways to improve the *cooperation and communication* around research, *data access*, and approaches to *testing and diagnosis*. They also stressed the need to *communicate research results* more effectively and, perhaps most important, the need for *expanded research resources and funding* for Lyme disease. Throughout, they suggested several specific ideas for patient-driven research to be explored further at a LymeX Research Workshop in the summer of 2021.

In addition to many ideas from the breakout sessions described in this report, CODE has identified 14 potential high-priority actions for a path forward. These include:

Patient-Driven Innovation

1. Build on existing digital tools and develop new ones to empower patients and improve research and treatment
2. Have HHS play a coordinating role with the Lyme community to promote innovation
3. Increase Federal and private support for high-impact innovation opportunities
4. Review and revise current treatment guidelines
5. Improve education on Lyme for clinicians, patients, and the general public

Patient-Driven Data for Research

1. Allocate more resources and funding for Lyme disease research
2. Develop the Lyme research agenda with patient involvement and input
3. Develop a clinical case definition for people with persistent symptoms of Lyme disease
4. Support scientific collaboration on Lyme disease research
5. Bring “invisible” and underrepresented groups into the research process
6. Improve data sources and platforms for research

7. Strengthen the ethical governance of patient data
8. Support R&D to improve testing and diagnostics
9. Publish more studies of Lyme disease in the medical literature

This report, prepared by the independent Center for Open Data Enterprise (CODE), represents a summary of the LymeX 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 ideas from those discussions and are not meant to represent a formal consensus of the group.

This report was produced by the Center for Open Data Enterprise as part of the LymeX Innovation Accelerator. 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 *LymeX Roundtable: Bridging the Trust Gap*, the U.S. Department of Health and Human Services, or any other component of the federal government.

DISCLAIMER: Readers should not consider this document or any part of it to be guidance or instruction regarding the diagnosis, care, or treatment of tick-borne diseases or to supersede in any way existing guidance.

Introduction

Lyme disease is the most common vector-borne disease in the United States. The Centers for Disease Control and Prevention (CDC) estimates that 476,000 new U.S. cases emerge each year—more than **HIV/AIDS** and **invasive breast cancer** combined. **Direct medical costs** could reach \$1.3 billion each year for Lyme disease alone, with significant increases when therapy fails to return patients to baseline health. To address the urgency of this epidemic, the **U.S. 21st Century Cures Act** of 2016 (H.R.6) includes a section “to accelerate improved methods for prevention, diagnosis, and treatment of tick-borne diseases, including Lyme disease.”

Early diagnosis of Lyme disease is crucial for ensuring patients receive treatment as soon as possible, which can help prevent **late Lyme disease**. Today’s Food and Drug Administration (FDA)-approved diagnostic tests for Lyme disease are “indirect” tests, meaning they detect antibodies made by the human body in response to infection. The FDA has yet to approve “direct” diagnostic tests for Lyme disease, which would detect the presence or absence of an “active infection” — Lyme-causing bacteria in the human body. Healthcare providers consider a patient’s physical symptoms and the likelihood of exposure, either treating based on presumptive diagnosis or verifying through antibody testing. Antibodies to the Lyme-causing bacteria take several weeks to develop, so patients may **test negative if infected only recently**.

To facilitate patient-centered innovations, raise awareness, and incentivize next-generation diagnostics, the U.S. Department of Health and Human Services (HHS) and the Steven & Alexandra Cohen Foundation launched the LymeX Innovation Accelerator (LymeX), a public-private partnership. The mission of LymeX is to “accelerate Lyme Innovation progress and strategically advance tick-borne-disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government.”

On April 28 and 29, 2021, the nonprofit **Center for Open Data Enterprise** (CODE) co-hosted a *LymeX Roundtable: Bridging the Trust Gap* with HHS and the Steven & Alexandra Cohen Foundation to bring these stakeholders together and develop ideas for solutions. The LymeX Roundtable was hosted as part of the **LymeX Health+ (“health plus”)** methodology, which uses Human-Centered Design to focus on specific, high-impact health issues.

The LymeX Roundtable was an important step in continuing stakeholder engagement for Lyme disease solutions. It built on work begun in 2018 when CODE collaborated with HHS to host a **Lyme Innovation Roundtable**, which produced a **comprehensive report** that identified high-value datasets, emerging innovation for Lyme disease, and opportunities for better public-private partnerships across sectors. Findings and insights from that earlier Roundtable helped lay the groundwork for the LymeX partnership.

The April 2021 LymeX Roundtable focused on “Bridging the Trust Gap” because a lack of mutual trust and understanding among patients, doctors, researchers, and policymakers has been a major impediment to progress for Lyme disease. The LymeX Roundtable was designed to build trust by working in the open for visibility, transparency, and co-creation with patients, caregivers, policymakers, researchers, clinicians, and diverse stakeholders for progress in Lyme disease. Its purpose was to develop new, trust-building, inclusive approaches to patient-driven research and innovation to improve patient outcomes for Lyme disease. The LymeX Roundtable emphasized the critical importance of patient-driven research, open innovation, and open data, and ensuring that emerging data is collected, managed, and used in ethical ways transparently.

The LymeX Roundtable took place over two days. The first day featured a public Webinar with keynote addresses from Dr. Kristen Honey, HHS Chief Data Scientist and Senior Advisor, and Lorraine Johnson, the CEO of Lymedisease.org and principal investigator for MyLymeData, as well

as lightning talks on current approaches to Lyme Innovation. On the second day, CODE facilitated parallel, simultaneous breakout sessions that engaged 67 invited participants on two topics: *Patient-Driven Data for Research* and *Patient-Driven Innovation*.

This report synthesizes the discussions during those breakout sessions and presents a clear path forward for government officials, advocates, scientists, and other stakeholders in the Lyme community. Information and opinions in this report do not necessarily reflect the U.S. Department of Health and Human Services, or any other component of the federal government. Federal Advisory Committee Act (FACA) rules did not apply to the Roundtable, an invitation-only event designed to elicit individual views and input from experts in the field. This report is not meant to represent a consensus of Roundtable participants, but reflects CODE's analysis of individual participants' input and other research done before and after the Roundtable.

Patient-Driven Innovation

The **HHS Lyme Innovation initiative**, launched in 2018, is a patient-centered, data-driven approach to the serious threat of Lyme disease and other tick-borne illnesses. Since its launch, Lyme Innovation has developed new digital tools in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government. Lyme Innovation has produced several valuable data-driven innovations and digital solutions to improve Lyme research, patient outcomes, education, risk assessment, and prevention.

Through the Lyme Innovation initiative, HHS and other parties during the past decade have invigorated work on Lyme disease through user-centered strategies like crowdsourcing, data “hackathons,” and accelerators designed to bring new actors into the field and strengthen existing teams. These strategies go well beyond conventional apps: They include “citizen science” approaches that engage ordinary people in research and continuing medical education (CME) programs that use innovative outreach to educate clinicians about Lyme disease.

The April 2021 LymeX Roundtable explored existing tools and approaches and potential innovations that don’t yet exist but could have a particularly high impact. These ideas fall into several categories, including digital tools, surveillance information, education, and community.

Apps and Digital Tools

Many digital tools focus on the infection process, provide education to prevent infection, or help track the location and prevalence of infections, or enable patients to track their symptoms and share data if they so choose. **TickTracker** helps users report on the ticks they find and tracks ticks in real-time, while **TickCheck Tick ID** provides free tick identification services and valuable resources on Lyme disease, tick removal, and other tick-borne diseases. **The Tick App** provides information on ticks, daily activity logs to help guide research, and the option to send pictures of ticks for identification. Newer efforts discussed at the LymeX Roundtable include an artificial intelligence (AI) powered tool that identifies the “bulls-eye” rash often associated with Lyme disease, using cell phone photos.

Patients can use apps like these to collect their data and share it for research if they so choose. Individuals with Lyme disease can use wearables like the Apple Watch or **Oura Ring** to track vital data and leverage a variety of new tools to track their symptoms. They may also use online portals and conventional websites to track their symptoms and share information for research.

Roundtable attendees identified several opportunities to build on existing digital tools and leverage their data to empower patients, serve a more inclusive community of individuals with Lyme, and improve research and treatment. Specifically:

- *Developing new and existing tools in languages other than English* to help underserved populations access information and care. Many existing tools are only available in English. For example, few Spanish language resources are available to the large Spanish-speaking population with Lyme disease in California.
- *Upgrading “quantified self” tools to track additional symptoms* — including hard-to-track ones like fatigue — to monitor reactions to treatments and to integrate with systems for clinical follow-up and research. Data integration with existing research systems may build credibility for “quantified self” data within clinical and research communities through comprehensive symptom reports and side effect tracking for specific treatments.
- *Combining existing AI applications to provide a more holistic picture of the disease.* For example, it would be very helpful to have an app that can use AI to identify the “bulls-eye”

rash, discern between different tick types, and estimate how long a tick has been attached to measure the risk of infection. This sort of tool could be made even more powerful by enabling it to assess infection in animals and people. An app that combined these capabilities would appeal to a large audience and potentially attract sustainable funding, a significant hurdle to scaling that Roundtable participants identified.

- *Enabling “Lyme Literate” doctors (LLMDs) to expand their use of telemedicine* in the wake of COVID-19. Patients in areas where Lyme is not as well known could seek care from more knowledgeable clinicians. Insurance companies could give LLMDs necessary support to expand their services in this way.

Surveillance Information

One category of apps and tools focuses on collecting, using, and disseminating surveillance data on ticks and the risk of infection. Data is being used to understand where ticks are currently a threat, where they are becoming endemic in new areas, and how quickly they are spreading. This data can be invaluable in raising public awareness, preventing infection, and helping people with Lyme disease understand patterns related to their infection with the disease.

The CDC has developed programs for **tick surveillance** and **tick bite tracking**. Overall, the CDC’s existing surveillance efforts are an important starting point that can be built on to continue serving the Lyme community.

Watching how tick-borne diseases spread in animals is another important way to understand how they may spread among humans. Efforts like the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) **National Wildlife Disease Program** oversees the nationally coordinated Surveillance and Emergency Response System (SERS) to help states, federal agencies, and local authorities respond to emerging wildlife-related emergencies. **CAPCVET.org** tracks the spread of diseases in pets, provides expert articles and resources for policymakers, and features parasite prevalence maps.

While some surveillance efforts provide high-quality open data for researchers, clinicians, policymakers, and individuals with Lyme, LymeX Roundtable attendees identified how existing efforts and data could be improved, expanded, and made more useful to support better tools and resources for researchers, physicians, patients with Lyme, and the public at large.

- *Enable the CDC to explore adding new data sources and innovative techniques to their current surveillance methodologies.* These may include positive test results for ticks and tick-borne pathogens and increased surveillance of minority communities and other underrepresented communities (i.e., Latinx communities, pregnant women). They can also identify areas for additional data aggregation. Finally, the CDC could explore automated surveillance methods when more manual approaches may not be feasible or cost-efficient.
- *Train public health officials on additional methods to monitor and map the spread of ticks across the United States.* As a start, they can use national tick testing data to monitor the spread of tick-borne illnesses. The CDC could also develop data visualizations and simulations to explore how ticks may spread over the next 5-20 years. This can serve as an educational tool and early warning system for areas that may see future spikes in Lyme disease. Other useful methods for tracking the spread of Lyme and other tick-borne illnesses include:
 - *Using public data sources like Google searches* to monitor interest in tick-related issues and predict the spread of ticks.
 - *Using AI techniques to monitor pharmaceutical prescriptions and specific antibiotic regimens, emergency department visits, insurance data, clinical data showing symptom clusters, and other variables* to identify the spread of tick-borne diseases.

- *Leveraging the **One Health** approach to use animals as sentinels for the spread of Lyme.* Include veterinary biologists, the USDA, and other stakeholders involved in animal testing and monitoring to better understand how Lyme spreads among animals and what that may mean for the human spread of the disease.
- *Developing and encouraging more citizen science projects to map the spread of tick-borne illness.*
- *Enable public health officials to improve coordination and reporting between medical providers and state and local public health authorities, and then between state and local authorities and the CDC. The Federal government could provide additional funding for vector-borne disease surveillance efforts on a state-by-state level to improve this type of reporting.*
- *Translate surveillance data into educational programming to encourage prevention behaviors.* Data could be transformed into educational infographics or serve as the basis for targeted education campaigns tailored to conditions in specific states or regions.

Education

While LymeX Roundtable participants saw a need to educate many groups about Lyme disease, the current education programs they described are geared to physicians. Several continuing medical education (CME) courses currently exist or are under development that focus on spreading awareness of different aspects of Lyme disease to clinicians who may not have adequate or up-to-date knowledge. High-impact areas include neurology, immunology, and pediatric Lyme. Invisible International's **Montecalvo Platform for Tick Borne Illness Education** was cited as a particularly useful example of CME innovation. For example, the **"7 years of blood-based Lyme disease testing"** module helps physicians assess the frequency of Lyme disease cases in the United States as reported by the CDC and better understand the advantages and limitations of the laboratory case definition of Lyme disease testing.

LymeX Roundtable participants articulated the need for additional education for clinicians through CME courses, free webinars, and better tools to diagnose and treat Lyme, especially for physicians in areas with no long history of Lyme disease as well as for individuals with Lyme and the general public.

- **For Clinicians**
 - *Enable CME providers to develop a variety of new courses around Lyme.* They can focus on congenital Lyme and Lyme in pregnancy, Lyme co-infections, and symptomatology, and on reaching specific groups of healthcare professionals such as psychologists and psychiatrists.
 - *Enable government agencies and Lyme advocacy groups to conduct direct outreach to physicians where Lyme disease is an emerging issue.* For example, the CDC could run a direct marketing campaign among physicians, acknowledging Lyme as a real and growing problem.
- **For Individuals With Lyme**
 - *Patients need to be educated about Lyme and given resources that empower them to self-advocate.* Medical groups, patient advocacy groups, government agencies, or others could develop a resource that combines relevant information from "quantified-self" apps and symptom trackers to help individuals with Lyme understand their situation and advocate for themselves. These resources could also include print or online information sources.

- **For the General Public**
 - *Enable the federal government to develop and distribute a national educational program tailored to small communities without the resources to develop their own tick-borne illness, awareness, and prevention programs. HHS or other government agencies could also develop:*
 - *Education programs that emphasize prevention and are targeted towards changing social behavior*
 - *Education programs targeted towards underserved communities including minority groups, children, pregnant women, people in communities where Lyme is becoming endemic, and more*

Community, Connection, Convening, and Coordination

For individuals with Lyme, connecting to a broader community offers advantages, including education, access to treatment, mental health support, and more. Roundtable participants identified social media communities, awareness campaigns, and the increasing prevalence of chatbots, which can help with education, mental health support, and more as approaches to building community and connection.

LymeX Roundtable participants offered their own resources to support coordination and convening efforts. Lyme-focused nonprofits offered to increase coordination amongst themselves, with a specific focus on developing and promoting new CME courses. Advocacy groups offered to connect with insurance companies to make a case for a strong return on investment in developing proper Lyme diagnostics and treatment. Invisible International is **researching** funding, education, and research priorities for tick-borne illness. Participants discussed whether HHS could potentially offer shared services to Lyme organizations, patients, caregivers, providers. And participants from HHS expressed interest in seeking out more input from Lyme stakeholders on improving government efforts.

LymeX Roundtable participants also identified a major need for a more consistent, multidisciplinary approach to coordination and convening across the Lyme community. This approach would fully engage patients and provide opportunities for collaborative assessment and reassessment of research. Participants pointed out that HHS is well-suited to play a coordinating role and bring more visibility to ongoing efforts. Specific ideas included:

- *A symposium or conference focused on bringing technology to patients*
- *A center of excellence to help patients find information and resources on symptoms, care, and treatment in one place*
- *A “red team” effort to bring together stakeholders and challenge existing assumptions, or other programs that bring diverse teams together to innovate.¹*

¹ Red Teams are offensive security professionals who play the role of an enemy or a competitor to break down another team’s defenses to expose security issues or general flaws in a system. They are often used in military settings to help policymakers and planners address evolving threats.

Patient-Driven Data for Research

With the Lyme community, government, and medical experts calling for increased research, there is a unique opportunity to collect, aggregate, and analyze patients' experiences in new ways to inform research on Lyme disease. This new data can ultimately improve diagnosis, patient outcomes, and the patient experience.

Emerging technologies and innovative digital tools can help illuminate the complexities surrounding Lyme disease and provide new ways to measure the patient experience. With the advent of crowdsourcing, citizen science, and digital resources, both patients and researchers can collect information at scale, empowering everyone to engage in data collection, research design, and scientific discovery. For example, wearable technologies can transform complex Lyme disease symptoms — often “invisible” symptoms such as sleep disturbances and heartbeat irregularities — into visible, measurable, quantitative data points.

Patient registries for people with tick-borne diseases — such as [MyLymeData](#), which has had over 14,000 patients contribute their data so far — can be a model for incorporating Lyme disease patients' reports of their experiences into academic and peer-reviewed research. Further, they offer data governance models, data ethics, informed consent, and patient-practitioner relationships where patients have the agency to drive decisions and guide research.

Whatever data sources are used, they must be developed with strong patient guidance on the ethical use of data, including ensuring individual data privacy and security. The Lyme disease community needs to have a meaningful voice and a permanent seat at the table in shaping research priorities, studies, data use, and ethics.

Benefits and Challenges of Patient-Driven Research

LymeX Roundtable participants described many benefits of engaging patients in research — not only to volunteer to share their data but also to help shape the research agenda. Patients have a unique perspective on symptomatology based on their own experiences. They can provide practical insights to help researchers understand different symptom categories and types of Lyme disease cases. Furthermore, including diverse patient voices in the research process can build trust between patients and researchers while improving research outcomes.

Researchers can use data that patients voluntarily provide to gain new insights about the lived experiences of individuals with Lyme and move research in new directions. For example, MyLymeData pools data on patient experiences, symptoms, treatments, and results and takes a patient-driven approach to use that data for research. The [Stanford Health Innovation Lab](#) is a model that works to connect patients and clinicians and leverages data from wearables and other sources to advance precision medicine in various areas. Projects like [Documenting Hope](#) have demonstrated the value of patient-driven data collection with their Child Health Inventory for Resilience and Prevention study, ensuring that parents can help understand chronic health conditions in children.

Biobanks, such as [the Bay Area Lyme Foundation's Lyme Disease Biobank](#), provide another model for patient-driven research. The Biobank works to obtain and characterize critical blood, urine, and tissue samples from untreated patients with early-stage Lyme disease and patients with chronic disease, as well as tissue samples from late-stage Lyme patients. This program helps improve research efforts to accelerate medical breakthroughs in the understanding, diagnosis, and treatment of Lyme disease and other tick-borne infections.

While the benefits are clear, however, several obstacles stand in the way of truly patient-driven research. LymeX Roundtable participants identified many challenges that researchers, clinicians, and the Lyme community can begin to address as we develop research models with greater patient engagement.

Cultural Challenges

Cultural challenges impact patients, researchers, and other stakeholders and ultimately hinder patient-driven research. There are sometimes discrepancies between what patients want to see research accomplish and what scientists believe they can study - a gap that may make patients reluctant to participate in research. At the same time, researchers and research funders may have difficulty incorporating the complexity and diversity of patients' experiences in their research models. There are limited opportunities or incentives for institutions to engage with patients, fostering distrust among both parties.

Data Challenges

There are many challenges in incorporating patient data into research. There has been a lack of reliable metrics on the symptoms that individuals with Lyme experience throughout the course of the disease (a problem that some of the innovations discussed earlier in this report may alleviate). Biases in self-reported data may mean a dataset is not representative of the actual Lyme population. And complications in cohort research due to co-infections and previous treatment may impact data quality.

Clinical data on Lyme disease has the same limitations that affect all clinical data for research. In the absence of universal, standardized electronic medical records, relevant data is often stuck in PDFs or other static sources. These sources could be converted to machine-readable data, and clinical data could be collected in machine-readable formats. Additionally, clinical offices could be encouraged to harness and distribute high-quality patient data with appropriate patient permissions and privacy protections. LymeX Roundtable participants shared that free tools can be developed to help small practices share their data. CODE's website on this topic, [HealthDataSharing.org](https://www.healthdatasharing.org), provides a range of information and resources designed to facilitate this.

Finally, LymeX Roundtable participants noted that data on patients is now siloed and separated from data on disease vectors. Researchers need better ways to integrate those data sources to gain new insights into Lyme disease and ultimately improve patient outcomes.

Trust, Ethics, and Privacy

A lack of mutual trust and understanding among patients, doctors, researchers, and policymakers has been a major impediment in Lyme progress. There is a clear need to build trust so that the Lyme community, researchers, and policymakers can work together towards more positive outcomes.

While Lyme research, like other medical research, is already subject to review by independent review boards (IRBs), better communication and engagement are needed to ensure that patients understand how their data is protected and help determine how it's used. Some current government research programs, including the [All of Us Research initiative](#) and the [Million Veteran Program](#), have developed approaches for ensuring patient consent for data use. However, LymeX Roundtable participants emphasized that guidelines for data use need to be developed with more direct patient involvement, using MyLymeData as a possible model.

Research Needs and Opportunities

Discussion at the LymeX Roundtable surfaced several specific needs and opportunities related to Lyme disease research and data collection. They fall into several categories: collaboration and communication, data access and use, testing and diagnosis, communication of research results, and resources and funding.

Collaboration and Communication

Collaboration is vital to developing more patient-driven research for Lyme disease. LymeX Roundtable participants identified several opportunities to develop new collaborative structures and partnerships on research and communications. They also discussed a role for HHS to improve trust between communities by hosting more collaborative convenings that bring together stakeholders to break down silos and promote more engagement and outreach from researchers towards patients.

The Lyme community needs to leverage new and existing relationships and structures to build trust and advance research around Lyme disease. This can come in data sharing, working across communities to design new approaches to research, and collaborating with new or under-engaged stakeholders on important issues. Ideas that emerged during the LymeX Roundtable include:

- *Establish a multicenter network* to enable physicians and scientists to communicate on projects, ask for samples, collaborate on grants, and share prospective clinical trials. This could include an interactive hub that can help expedite research on Lyme disease and develop a well-characterized biorepository for clinical blood and tissue samples.
- *Collaboration between the private, academic, government, patient, advocate, medical and other communities on a variety of research initiatives.* For instance, patients, advocates, and the medical community need to work together to decide the best ways to track and use symptom data combined with direct blood tests.
- *Collaboration between foundations* with deep knowledge of research areas and agendas and the National Institutes of Health (NIH) aligns objectives and goals, sets standards for diagnostics, aligns funding, and shares results and insights.
- *The government, researchers, and Lyme organizations can collaborate on specific research projects.* For example, Invisible International is doing its own clinical trials. They proposed collaborating with HHS to provide meaningful context (i.e., better symptom identification using government resources) through a common symptom list to fast-track diagnostics.
- *The Lyme community can make the space more inclusive — with less top-down authority from institutions — and identify and incorporate “invisible” communities specifically.* For example, mothers concerned about infecting their unborn children have their voices heard.

Improving Data Access and Use for Research

Improved data can be used to build trust by streamlining and speeding up the research process across various areas including surveillance, integrating new data sources, and building better biobanks.

- *Improving surveillance data:* Government sources have to continue to provide relevant, accurate, and up-to-date information. This includes continuing to refine approaches to accurately count both acute and persistent cases of Lyme disease through the use of emerging methods like automated survey collection.
- *Integrating new data sources:* More work needs to be done to streamline the transmission and processing of data, especially as more tools emerge that track and combine a wider variety of data, including symptoms, clinical data, and information on patient history. For example, Invisible International is currently setting up a **data repository** at ten university sites that will combine clinical and patient history data.
- *Building biobanks:* There is a significant need for better platforms that would connect clinicians to biological samples from patients at all stages of Lyme disease and share available treatments. These biobanks could build on existing efforts to examine suicide risk factors, violence, substance abuse, and addiction tied to Lyme disease or integrate other data sources. Moreover, they can be combined with volunteered patient data to paint a broader picture of the Lyme diagnostic landscape and advance research on diagnosis and

treatment. In addition to building on the existing Lyme Disease Biobank, it may be helpful to review and learn from other models, such as the National Cancer Institute's [Biorepositories and Biospecimen Research Branch](#).

Testing and Diagnosis

It is difficult to properly treat tick-borne illness and study the diversity of Lyme cases and patient journeys without proper diagnostic testing. Currently, individual clinicians rely heavily on their own, widely variable, background knowledge for diagnostics. Specialized Diagnostic labs like [IGeneX](#) can aid in the rapid development and evaluation of novel treatments, provide large data sets on national test results, and invest in and drive novel technologies into use. Before the CDC will recommend new diagnostic tests, they must be cleared by the FDA. For more details, see: [Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease](#).

Other aspects of the LymeX initiative are addressing the challenges of testing and diagnostics more deeply. However, LymeX Roundtable attendees identified several ongoing innovations in testing that they have found valuable.

- **New Testing and Diagnostics Technologies**
 - LymeX Roundtable participants highlighted several new testing and diagnostic technologies. These include a test **that** aims to distinguish between early and late stage cases of Lyme disease and [Nanotrap technologies](#) that make testing easier and potentially more accurate.
- **New and Innovative Diagnostic Laboratories and Programs**
 - LymeX Roundtable participants highlighted multiple laboratories specializing in Lyme diagnosis, including [TickCheck](#), which accepts tick samples through the mail and conducts tests within 48 hours, and [IGeneX](#), which tests for a wide range of tick-borne illnesses. Laboratories like [TickLab.org](#) can test for factors like the duration of tick attachment and a range of relevant pathogens. The Department of Defense (DoD) also has a unique program called [MilTICK](#) that provides free testing and identification for ticks removed from DoD personnel and their families.

Building on these positive developments, LymeX Roundtable participants identified several opportunities for improved testing. They expressed interest in possible partnerships between academia, the Federal government, and the private sector to drive the development of clinically accurate diagnostic tests and other tools. These include:

- *Blood panels that screen for the most common tick-borne diseases* including babesia, anaplasma, bartonella, and others to help identify multiple pathogen infections and distinguish between different types of tick-borne illnesses.
- *Incorporation of mold toxicity as well as antibodies, proteins, and other immune markers.*
- *Better screening and support for groups that may have been missed* in Lyme disease testing, including minority communities and pregnant women.
- *Better insurance coverage for a wider variety of tests*, including those from new and small labs, would encourage physicians to conduct more thorough tests when they suspect a patient has Lyme.
- *Better provider training* to help physicians understand patient symptomatology and when to administer tests for tick-borne illness.
- *Potentially, a national screening day for Lyme disease and other tick-borne illnesses* once accurate enough diagnostic tests are developed.

Communicating Research Results

As LymeX Roundtable participants discussed the benefits, challenges, and details of developing patient-driven research projects, they highlighted some important items for consideration including the need to connect researchers to data and the importance of communicating new research results to wider audiences. There was a significant discussion of the need to bring major, mainstream journals to the table to ensure that articles about Lyme are published and widely read by the broader medical and scientific communities. Other ideas to further communicate the results of Lyme research included hosting a research forum or offering cash honoraria for publishing case studies on patients who have multiple tick-borne diseases

Expanding Research Resources and Funding

LymeX Roundtable participants discussed ways to increase funding, devote available funding to additional priorities, or both. Some options include:

- *Have Congress consider more dedicated appropriations to address Lyme disease and fund research.*
- *Direct some NIH funding to prevention and treatment and basic research, where NIH funding for Lyme disease is currently focused.*
- *Encourage more Lyme disease researchers to apply for NIH grants in relevant granting areas.* For example, an informational resource could surface grant opportunities in maternal health that could explore concerns about Lyme in pregnancy.
- *Have Lyme disease research classified as a health security issue, which would unlock additional funding and resources through programs like the HHS's Biological Advanced Research and Development Authority (BARDA) **DRIVE program**, which provides resources to address emerging health threats. Beyond BARDA, the Lyme community could encourage the HHS Assistant Secretary for Preparedness and Response to support this approach.*

Next Steps: A Research Workshop

Building on insights from the *Patient-Driven Data for Research* breakout sessions, CODE is collaborating with HHS and the Steven & Alexandra Cohen Foundation to plan and conduct a follow-up *LymeX Research Workshop* in summer 2021. This Workshop will be a virtual event with 30-40 expert participants. The Workshop's purpose is to build on ideas from the Roundtable to develop a shared understanding of clinical research priorities, methods, and results between patients, clinicians, and researchers. It will be a unique opportunity to bring patients and advocates together with researchers to identify high priorities for research and ways to collaborate with the Lyme community. Participants will be chosen specifically for this Workshop, although there may be some overlap with LymeX Roundtable participants. The workshop will identify strategies to make patients truly valued and respected in the overall research process.

Policy Issues and Opportunities

Although health policy was not a specific focus of the LymeX Roundtable, policy issues were part of the breakout discussions on innovation and research. LymeX Roundtable participants emphasized that individuals with Lyme need to have a stronger voice in the government policy and funding process. For example, government panels that set guidelines have been criticized for ignoring or avoiding incorporating patient points of view in the past. As one possible strategy to address this gap, the **Tick-Borne Disease Working Group** (TBDWG) could emphasize transparency and reorient its mission to put a higher priority on community voices. The TBDWG has a platform to present agenda items and high-impact priority areas to Congress.

Some participants also raised policy changes in the medical approval process to support research and help build trust among the Lyme community. In particular, many Lyme patients would welcome changes to allow the FDA to speed approval for Lyme diagnostics or treatments. FDA approval for novel diagnostics would encourage insurance companies to provide coverage, which would, in turn, encourage more patients to get tested, which could save lives and provide valuable data for research.

Participants had several ideas for ways that the Federal government, private companies, and medical societies could change policy or guidance to make it easier to diagnose, treat, and conduct research on Lyme disease. For example:

HHS

- *The HHS **Office of the National Coordinator for Health IT** could enable patients to take control of their data* by changing existing rules and writing new ones.
- HHS could work with the Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) to *understand if their value-based-care-payment models might be appropriate for Lyme Innovation.*
- HHS could expand existing efforts to address emerging healthcare threats like **BARDA DRIVE** to focus on tick-borne illnesses.

Other organizations and bodies:

- *Medical societies* could develop clinical guidance to help the medical community identify symptoms and diagnose Lyme disease. Participants also noted the need for new interim guidelines for Lyme and pregnancy and updating current testing and treatment guidelines.
- *The World Health Organization (WHO) could bring back the classification for congenital Lyme in future versions* of its **International Classification of Diseases** (ICD). WHO removed congenital Lyme from the 11th edition of the ICD.
- *Insurance Companies could add long term Lyme treatment programs to their systems.* There are no insurance codes for long term Lyme treatment. This makes physicians more hesitant to diagnose and treat Lyme disease because it is harder for them to be paid by insurers for doing so. These additions can be based on ICD-10 codes for standard Lyme disease symptoms.

High-Priority Actions for a Path Forward

CODE has reviewed the results of this LymeX Roundtable to synthesize 14 High-Priority Actions for a Path Forward: five on Patient-Driven Innovation, and nine on Patient-Driven Data for Research. Roundtable participants identified several ways in which HHS can play a leadership role in implementing these actions in collaboration with researchers, physicians, and the Lyme community. The upcoming LymeX Research Workshop will explore ways to put these research ideas into practice.

Patient-Driven Innovation

- 1. Build on existing digital tools and develop new ones to empower patients and improve research and treatment.** LymeX Roundtable participants identified a number of opportunities to develop new digital tools and applications and leverage existing ones. These include the following ideas:
 - Translate new and existing tools into additional languages to help underserved populations access information and care.
 - Upgrade “Quantified self” tools to track additional symptoms — including hard-to-track ones like fatigue — monitor reactions to treatments, and integrate with systems for clinical follow-up and research.
 - Combine existing AI applications to provide a more holistic picture.
 - Encourage “Lyme Literate” doctors (LLMDs) to expand their use of telemedicine, using capabilities that were developed during the COVID-19 pandemic.
- 2. Have HHS play a coordinating role with the Lyme community to promote innovation.** LymeX Roundtable participants emphasized the need for more multistakeholder convenings to bring those in the Lyme community together with researchers, clinicians, and other stakeholders. As a Federal leader, HHS can bring more visibility to ongoing efforts in Lyme innovation, host convenings to connect patients to technology, and develop a center of excellence to connect patients with symptom and treatment information, care, and other resources.
- 3. Increase Federal and private support for high-impact innovation opportunities.** Greater funding must be allocated to innovations in treatment, diagnosis, and education that may not have an immediate return on investment. Examples include supporting innovative companies to navigate regulatory issues, enabling ‘red team’ efforts on high-impact opportunities, and promoting novel technology efforts that may improve care or reduce the costs of treatments. These include machine learning and AI, voice -ssisted mobile applications, and enhanced clinical decision support for physicians.
- 4. Review and revise current treatment guidelines.** Conflicting views of the nature and course of Lyme disease have led to conflicting treatment guidelines, which can inhibit appropriate innovation. LymeX Roundtable participants shared that HHS could bring patients together with medical societies like the Infectious Diseases Society of America (IDSA) and the International Lyme and Associated Diseases Society (ILADS) to build a new consensus for clinical guidelines around Lyme diagnosis and treatment. Participants noted that the current guidelines used by large numbers of clinicians underestimate the length of antibiotic treatment necessary to treat Lyme and do not acknowledge the reality of persistent infections and the need for innovative methods to treat them.

- 5. Improve education on Lyme for clinicians, patients, and the general public.** Roundtable participants identified the need to educate all medical and Lyme community stakeholders on current Lyme information. Education needs include the following:
- *For healthcare clinicians:* CME providers could develop new courses for Lyme disease that focus on issues like congenital Lyme and Lyme in pregnancy, Lyme co-infections, symptomatology, and the psychoneurological components.
 - *For individuals with Lyme:* Better resources need to be made available to encourage them to self-advocate.
 - *For the general public:* The Federal government could develop and distribute a national educational program tailored to small communities who lack the resources to develop their own tick-borne illness, awareness, and prevention programs. Education programs targeted towards underserved communities and focusing on prevention could be developed as well.

Patient-Driven Data for Research

- 1. Allocate more resources and funding for Lyme disease research.** Lyme disease research is notably underfunded by comparison with other diseases, including some that affect a smaller number of people in the U.S. or may have a less severe impact. In addition to the potential for Congressional appropriations, some steps can be taken more immediately to increase funding. For example, the NIH could encourage the development of more focused, innovative studies using available grants. Additionally, the HHS Assistant Secretary for Preparedness and Response and Biomedical Advanced Research and Development Authority (BARDA) could classify Lyme disease as a health security issue, which would unlock additional funding and resources.
- 2. Develop the Lyme research agenda with patient involvement and input.** Particularly because funding is limited, researchers and funders must prioritize the goals of Lyme research - and patients must have a meaningful role in setting those priorities. Research organizations need to engage patients to ensure that their views are represented. As part of this process, HHS could conduct a **capability gap analysis** which can help determine what patients want to see out of research efforts and identify existing gaps. More immediately, the LymeX Innovation Accelerator will hold a Research Workshop in summer 2021 to explore and prioritize research ideas that were identified at the Roundtable and through additional research and discussions. Initial patient-driven ideas include research on the following subjects:
 - Understanding persistent Lyme symptoms
 - Developing case definitions for people with persistent Lyme symptoms
 - Developing accurate statistics on the number of people w/ persistent Lyme symptoms
 - Studying how research on long-haul COVID and persistent symptoms of Lyme disease may inform each other
 - Understanding the impact of Lyme disease in different groups
 - Developing guidelines on Lyme disease in pregnant women and young children
 - Studying the prevalence of Lyme disease in communities of color and challenges in diagnosis or treatment
 - Understanding the role of gender in Lyme disease risk
 - Identifying risk factors for Lyme disease, including occupation and SDOH factors

- Improving epidemiologic data and its use
 - Improving research for surveillance - including studies of animals (wildlife and pets), citizen science, and other approaches
 - AI monitoring of the spread of tick-borne diseases to analyze diverse data sources, such as Google searches, emergency department visits, and insurance, clinical, and prescription data
 - Evaluating available, innovative testing methods in parallel to basic research to produce a new, definitive Lyme diagnostic test
 - Improving patient outcomes
 - Understanding and addressing the mental health impacts of Lyme disease
 - Research on treatments for other infection-associated conditions that may be applicable to Lyme disease
- 3. Develop a clinical case definition for people with persistent symptoms of Lyme disease.** Both patients and researchers at the Roundtable identified this need as perhaps the highest-priority new area for research and one that is particularly urgent. A core issue in research, diagnosis, and treatment is the lack of agreement on whether and how Lyme infection can persist for years. Until better diagnostic tests are developed, researchers and clinicians will need to use patient data, analysis of symptoms, and other approaches to develop descriptions and nomenclature for the experience of people with persistent symptoms of Lyme disease. LymeX Roundtable participants stressed the importance of collecting and accessing data to make this analysis possible, including clinical data on patient symptoms through different stages of treatment and disease.
- 4. Support scientific collaboration on Lyme disease research.** HHS can strengthen its leadership role to build on the LymeX Innovation initiative and provide top-down and proactive support to the community of scientists working on Lyme and tick-borne diseases. LymeX Roundtable participants mentioned that HHS work with other stakeholders to:
- Build an interactive community hub where physicians and scientists can communicate on projects, ask for samples, collaborate on grants, and share initial results from clinical trials to expedite research
 - Coordinate research efforts between private, academic, government, patient, advocate, medical and other communities
 - Enable collaboration between foundations with deep knowledge of research areas and agendas and the NIH to align objectives and goals, set standards for diagnostics, align funding, and share results and insights
- 5. Bring “invisible” and underrepresented groups into the research process.** Currently, Lyme patients who become activists and volunteer their data for research are disproportionately white, female, and middle class. People of color seem to be particularly underrepresented in Lyme research. LymeX Roundtable participants also emphasized the importance of studying pregnant women and children with Lyme disease. Researchers can work with the Lyme community to engage more diverse, representative groups of Lyme patients in setting the research agenda and contributing their data for research.
- 6. Improve data sources and platforms for research.** Lyme researchers need both better surveillance data and better patient data. Government surveillance data must be relevant, accurate, and current, and must account for people with persistent symptoms and those with acute cases. Sources of patient data can improve, ranging from clinical records to blood

and tissue samples stored in biorepositories.

- 7. Strengthen the ethical governance of patient data.** With the growth of AI and machine learning and the potential to re-identify anonymized patient records, concerns over health data privacy have grown. Patients need to work with researchers to develop ethical guidelines for the use of their data, including ensuring data privacy and security. Additionally, patients often are not aware how their data will be used if they volunteer personal information for research, and fear the possibility of it being used against them, shared publicly, with employers, or other third parties. Patients need to be made aware of data protections that exist to keep them safe, which may incentivize them to share their much-needed information.
- 8. Support R&D to improve testing and diagnostics.** There is a clear need for research to develop better testing and diagnostics to capture the diversity of Lyme disease cases. HHS could encourage specialized diagnostic labs to aid in the rapid development and evaluation of novel treatments, provide large data sets on national test results, and invest in and drive novel technologies into use. HHS or private-sector experts could also offer help to specialized labs and diagnostic companies to navigate regulatory issues that come with moving a diagnostic to the patient space
- 9. Publish more studies of Lyme disease in the medical literature.** Several LymeX Roundtable participants noted that major mainstream journals publish little research related to Lyme disease. Academic, government, and private sector researchers could explore why this is and develop strategies to increase medical publication. In addition to being essential for scientific progress, the publication of more studies at this level would help encourage researchers to enter the field.

Conclusion

The LymeX Roundtable was a project of the LymeX Innovation Accelerator, which seeks to accelerate **Lyme Innovation progress** and strategically advance tick-borne disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government. At the April 2021 LymeX Roundtable, individuals with Lyme, caregivers, clinicians, researchers, and the private sector discussed the most salient challenges and potential opportunities to address these challenges. This report highlights these issues and solutions to advance Lyme disease research and develop novel data-driven innovations.

The geographic habitat range of ticks, mosquitoes, and fleas that can transmit pathogens and cause disease has **expanded within the United States**. The development and survival of ticks, their animal hosts (such as deer), and the bacterium that causes Lyme disease are all **strongly influenced by climatic factors**, especially temperature, precipitation, and humidity. HHS has an opportunity to take the lead on cross-sectoral efforts to take on this growing crisis. The LymeX Roundtable identified areas of research and innovation in need of immediate action. Opportunities include prioritizing patient perspectives in research agendas and developing new resources and digital tools to track the spread of Lyme disease. With more funding, collaborative convenings, and true patient prioritization, we have a historic opportunity to move the needle on Lyme disease treatment, prevention, and diagnosis.

Acknowledgments

The *LymeX Roundtable: Bridging the Trust Gap* was held as part of the LymeX Innovation Accelerator, a public-private partnership between HHS and the Steven & Alexandra Cohen Foundation. The organizers of the LymeX Roundtable included Paul Kuhne, Temilola Afolabi, Joel Gurin, and Matt Rumsey of CODE; Kristen Honey and Alex Wilson of HHS; Bennett Nemser of the Steven & Alexandra Cohen Foundation; and Jason Hairston and Laura Porter of Pistis. CODE also thanks LymeX participants Coforma and Ensemble for their support. This Summary Report was written by Matt Rumsey with the editorial support of the CODE team.

Appendix I - List of Acronyms

AI artificial intelligence

APHIS Animal and Plant Health Inspection Service

BARDA Biological Advanced Research and Development Authority

CDC The Centers for Disease Control and Prevention

CME Continuing medical education

CMMI Center for Medicare and Medicaid Innovation

CMS Centers for Medicare and Medicaid Services

CODE Center for Open Data Enterprise

DoD Department of Defense

FACA Federal Advisory Committee Act

FDA Food and Drug Administration

HHS The U.S. Department of Health and Human Services

ICD International Classification of Diseases

IDSA Infectious Diseases Society of America

ILADS International Lyme and Associated Diseases Society

IRBs Independent review boards

LLMDs “Lyme Literate” doctors

LymeX LymeX Innovation Accelerator

NIH National Institutes of Health

SERS Surveillance and Emergency Response System

TBDWG Tick-Borne Disease Working Group

USDA U.S. Department of Agriculture

WHO World Health Organization

Appendix II - Roundtable Background Materials

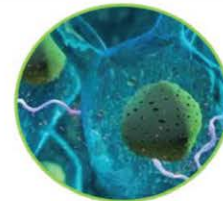


History of Lyme Innovation

HHS Lyme Innovation is a **patient-centered, data-driven approach to the serious threat of Lyme disease and other tick-borne illnesses.**

The Lyme Innovation initiative launched in 2018. It uses collaboration, data-driven innovation, emerging technologies, and strategic partnerships to accelerate advancements in Lyme and tick-borne diseases.

Lyme is an Exponentially Growing Challenge



~476,000

Americans diagnosed and treated for Lyme

59% Increase

Then previously estimation of 300k infected

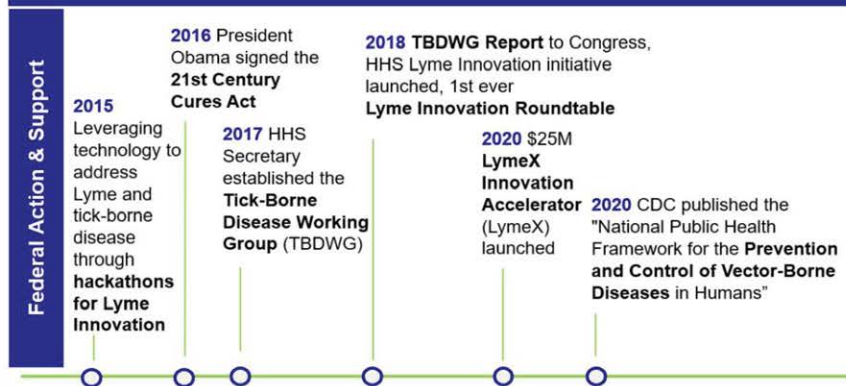
~ 90,000

Become persistently-ill

77%

of all Vector-Borne Diseases

Lyme Innovation Timeline



LymeX Public-Private Partnership

Due to limited federal appropriations and support, the LymeX Innovation Accelerator (LymeX) launched in 2020. The LymeX mission is to **strategically advance tick-borne-disease solutions in direct collaboration with Lyme patients, patient advocates, and diverse stakeholders across academia, nonprofits, industry, and government.** Three focus areas are:



Patient-Centered Innovations	Education and Awareness	Next-Gen Diagnostics
<p>Execute human-centered design methods in identifying, developing, and implementing advancements in Lyme disease care that foster innovations which can deliver transformative improvements on patients' quality of life.</p> <p>Identify common challenges in patient and healthcare provider experiences.</p>	<p>Focus on innovative health education that brings light to tick-borne disease prevention using open innovation methods.</p> <p>Highlight and expand public awareness on initiatives to help clinicians, patients, and caregivers benefit from the latest scientific findings.</p>	<p>Establish prize challenges open to universities, non-profits, and private sector that encourage rapid, cross-sector, patient-centered diagnostic innovations.</p> <p>Drive creators, industries, and academia toward breakthroughs in more accurate Lyme diagnosis, helping make next-gen diagnostics available more quickly.</p>

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Questions? Email LymeInnovation@hhs.gov

Patient-Driven Innovation

Launched in 2018, the HHS Lyme Innovation initiative is a patient-centered, data-driven approach to the serious threat of Lyme disease and other tick-borne illnesses.

User-Centered Approaches

Crowdsourcing	Data "Hackathons"	Accelerators	Citizen Science
A call to the public for technology solutions, following the wisdom that the best ideas come from contributions from a diverse set of individuals.	An event where experts gather to rapidly develop technology solutions to a defined problem statement, often utilizing public open data.	A program to rapidly bring an idea to fruition. The goal of an accelerator is to help scale an idea in a compressed amount of time.	General public participation in scientific research. The public participates voluntarily in the scientific process, addressing real-world problems.

Resources & Examples

Tick-focused innovation: Available digital tools that focus on the infection process, provide education to prevent infection, or help track the locations and prevalence of infection.



- TickTracker
- TickCheck Tick ID
- The Tick App

"Quantified self" tools to transform invisible symptoms into visible data: Emerging technologies can make historically invisible illnesses visible by quantifying hard-to-track symptoms, such as tachycardia and sleep disturbances.



- Heart and blood pressure monitors
- Sensors for respiration, temperature, and blood oxygen

Virtual caregiver and patient support: Help people with Lyme and other illnesses to track their symptoms, improve access to practitioners who specialize in Lyme disease, or provide virtual caregiver functions.



- Support Group Finder
- Lyme Symptom Tracker
- My Pain Diary

Clinical resources: Help educate physicians and other healthcare providers about Lyme by making new research easily accessible or drawing attention to issues such as the potential mental health impact of the disease.



- CDC Tick-borne Diseases app
- Medical education resource guide on tick-borne illnesses

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Patient-Driven Data for Research

With crowdsourcing, citizen science, and digital resources, both patients and researchers can **collect information at scale, empowering everyone to engage** in data collection, research design, and scientific discovery.

There's an opportunity to collect, aggregate & analyze patients' experiences in new ways to inform Lyme disease research.

Goals

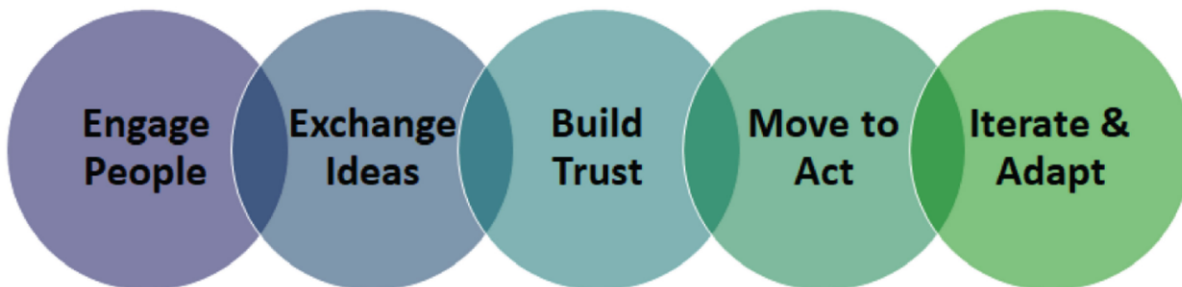
Translate Lyme Experiences	Engaging People	Open Data Sharing	Public-Private Collaboration
Explore key issues in using patient-generated data and how best to translate patients' experiences with Lyme disease into data.	Identify opportunities to meaningfully engage patients and leaders in driving today's Lyme disease research priorities and new research collaborations.	Identify and discuss sensitive issues related to appropriately handling and applying patient-generated data to support patient-driven research.	Identify opportunities for public-private partnership and collaboration among patients, leaders, clinicians, researchers & policymakers.

Innovation

- Emerging technologies and digital tools can transform **complex Lyme disease symptoms** — often “invisible” symptoms such as sleep disturbances and heartbeat irregularities — into **visible, measurable, quantitative data**.
- Using data from new sources, such as **telemedicine, social media content, or volunteered medical information** from patient registries and biobanks.

In Action

MyLymeData	Lyme Disease Biobank
<ul style="list-style-type: none"> The largest patient registry for tick-borne diseases, 14,000 patients contributing to date Transform individual experiences into crowdsourced information Data analytics/bioinformatics shed light on symptoms, disease progression, patient outcomes Model for patient experiences into academic/peer-reviewed research 	<ul style="list-style-type: none"> Works to obtain and characterize critical blood, urine, and tissue samples from untreated Lyme patients at all stages of the disease Helps improve research efforts to accelerate medical breakthroughs in the understanding, diagnosis, and treatment of Lyme disease and other tick-borne infections



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Lyme Diagnostics: Challenge Brings Opportunity

Prompt diagnosis and treatment of tick-borne diseases are crucial to prevent long-term complications. Today, available diagnostic tests can be inaccurate and complex to interpret, especially during the earliest stage of infection when treatment is most effective.

Lyme is an Exponentially Growing Challenge



Lyme Disease is Widespread

Almost 500k people infected yearly in the U.S. and 90,000 become persistently-ill

No Direct Diagnostic Test

No FDA approved diagnostic test to detect the presence/absence of an "active infection"

Antibodies Take Several Weeks to Develop

Patients may test negative to the Lyme-causing bacteria if infected only recently

Missed Diagnoses

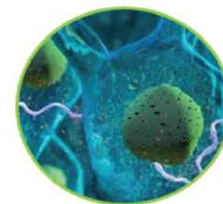
Treatment most effective when diagnosed early, but test results may be negative early

Serological Testing

The current two-tier serologic testing also does not always recognize Lyme symptoms

"Bulls-eye" Rash Not Always Prevalent

Up to 30% of patients do not experience the appearance of erythema migrans (EM) rash



~476,000

Americans diagnosed and treated for Lyme

59% Increase

Then previously estimation of 300k infected

~ 90,000

Become persistently-ill

77%

of all Vector-Borne Diseases

Potential Solutions

Diagnostic Tools

Diagnostic tools that directly measure tick-borne pathogens instead of testing for immune responses to Lyme disease.

Improved Diagnostic Tests

Developed by private-sector medical research labs, these would have to meet FDA requirements to assess the quality, sensitivity, and specificity of tests.

Testing Criteria

A standardized set of criteria for third-party diagnostic companies to meet before advertising and selling diagnostic tests to better protect consumers/patients.

How HHS is Working to Address Challenges

The LymeX Innovation Accelerator (LymeX) partnership issued a **Request for Information (RFI)** on Lyme disease diagnostic tests. This LymeX RFI gathered information on the **current state of the science and development of Lyme disease diagnostic tests**. HHS will publish a synthesis of RFI results in 2021, which will be used for framing a series of **multi-million-dollar grand prize challenges** to improve diagnostics at all stages of Lyme disease.

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Appendix III - Participating Organizations

Lyme Champions

Bay Area Lyme Foundation is a national organization committed to making Lyme disease easy to diagnose and simple to cure. A 501(c)3 non-profit organization based in Silicon Valley, Bay Area Lyme Foundation collaborates with world-class scientists and institutions to accelerate medical breakthroughs for Lyme disease. It is also dedicated to providing reliable, fact-based information so that prevention and the importance of early treatment are common knowledge. A donation from The Laurel STEM Fund covers overhead costs and allows for 100% of all donor contributions to Bay Area Lyme Foundation to go directly to research and prevention programs.

Center for Lyme Action is a 501(c)4 dedicated to growing federal funding for Lyme disease in an effort to find a cure -- especially for Lyme patients with persistent, debilitating symptoms. Our values are: bi-partisan, inclusive, humane, and scientific.

Central New York Lyme & Tick-Borne Disease Alliance is a collaborative of providers, scientists and community members who support research, drive education and promote awareness to combat tick-borne diseases.

Colorado Tick-Borne Disease Awareness Association is a 501(c)3 non-profit founded in 2016 to promote education, prevention, research and advocacy regarding Lyme and other tick-borne diseases for Coloradans.

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.

Hudson Valley Lyme Disease Association takes a holistic approach to health, and specializes 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.

LivLyme Foundation has a mission 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.

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

LymeHope is a Canadian not-for-profit organization dedicated to education and outreach on the subject of Lyme & related diseases in Canada. Their current area of focus is around maternal-fetal transmission of Lyme disease with a specific goal of advancing scientific and clinical knowledge by supporting and encouraging collaborative research.

LymeTV is a volunteer-based 501(c)(3) registered non-profit organization dedicated to educating the global community about Lyme disease & other dangerous tick-borne infectious diseases located worldwide.

Lyme Center of Martha's Vineyard is a place to get free information about Lyme Disease and the other common tick-borne infections and their prevention and treatment.

Lyme Disease Association 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.

Lyme Disease Foundation now 33 years old, is the premier Lyme advocacy and medical group founded by patients and researchers, including the discoverer of the Lyme bacterium in 1988, when no other such group existed. We have focused on basic science and scientific accuracy, as well as advocating for patient experiences. We obtained the first Lyme funding for the government. We have organized and sponsored 23 international tick-borne conferences that include experts from around the world and transformed the public's knowledge of tick-borne disorders.

Midcoast Lyme Disease Support & Education was created and exists to raise awareness, foster education, advocate for change and provide support for those affected by Lyme Disease and other tick-borne associated diseases.

NatCapLyme is an all-volunteer nonprofit, 501(c)(3) organization dedicated to improving the lives of those suffering from Lyme and other tick-borne illnesses. Their mission is to improve the quality of life for people suffering from Lyme and other tick-borne diseases by offering support and disseminating information to empower patients, families, healthcare workers, and the community at large.

The Patient Centered Care Advocacy Group advances comprehensive primary care to improve health and health care for patients and their families by convening and uniting stakeholders around research, care delivery and payment models, and policies.

SilverLeaf Consulting, LLC helps in commercializing new products. SilverLeaf Consulting leverages their extensive experience to supply 'on-demand' consulting, largely across 3 key areas: new product development, launch strategy and brand/sales execution.

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.

Texas Lyme Alliance is a science based advocacy non profit whose mission is to advocate for Lyme families the right to health through treatment. Their goal is to bring patients a working diagnostic, an effective treatment, and the right to insurance coverage.

Tick Tock Naturals mission is to prevent insect vector diseases whenever and wherever possible. This includes all diseases carried by ticks, mosquitos, fleas and spiders all of which have now been isolated carriers of disease.

Union Square Medical Associates is a medical group practice located in Elizabeth, NJ that specializes in Internal Medicine.

Research and Science

Biogen discovers, develops and delivers innovative therapies worldwide for people living with serious neurological and neurodegenerative diseases.

Boston Children's Hospital is ranked the number one pediatric hospital in the nation by U.S. News and World Report. It is home to the world's largest pediatric research enterprise, and it is the leading recipient of pediatric research funding from the National Institutes of Health.

Center for Research on Biotoxin Associated Illnesses is a nerve, muscle, and bone research organization in Pocomoke, MD, which was founded in 1994.

Georgetown University is an academic and research institution that offers an educational experience that prepares the next generation of global citizens to lead and make a difference in the world.

Lyme Disease Biobank is a collection of more than 940 human biological samples that facilitates research of Lyme disease and other tick-borne infections. The Biobank is a Bay Area Lyme research program, working to obtain and characterize critical blood, urine and tissue samples for researchers.

Rutgers University is a leading national research university and the state of New Jersey's preeminent, comprehensive public institution of higher education. Established in 1766, the university is the eighth oldest higher education institution in the United States.

Stanford School of Medicine integrates a premier medical school with world-class hospitals to advance human health. The School of Medicine improves health through leadership, diversity and collaborative discoveries and innovation in health care, education and research.

State University of New York Adirondack has one of the largest, most comprehensive university-connected research foundations 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.

University of Minnesota Medical School, Duluth Campus was founded in 1972 with a mission to be a leader in educating physicians dedicated to family medicine, to serve the needs of rural Minnesota and Native American communities.

Clinicians

Flatiron Integrative Health and Nutrition core approach is focused on an understanding of how the entire body works together in harmony. As such, they focus on overall well-being as opposed to simply improving the status of one individual condition or function of one individual organ.

Internal Medicine of Northern Virginia takes an overall integrative approach in the management of Lyme disease, with consideration of the microbiome, as well as other entities such as biotoxin illness, and mast cell activation syndrome.

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.

Milwaukee Alternative Medicine Center is committed to treating the whole person. Their fellowship-trained team of integrative medicine experts includes doctors, nurse practitioners, physician assistants and advanced practice providers committed to your physical, emotional and spiritual wellbeing.

University of Massachusetts Medical School's mission is to advance the health and wellness of our diverse communities throughout Massachusetts and across the world by leading and innovating in education, research, health care delivery and public service.

Department of Health and Human Services

The Centers for Disease Control and Prevention (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 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.

National Institutes for Health (NIH) seeks 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 Office of the Assistant Secretary for Health (OASH) oversees 12 core public health offices- 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 Office of the Assistant Secretary for Preparedness and Response (ASPR) leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies.

The Office of the National Coordinator for Health Information Technology (ONC) works to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

Other Federal Departments and Agencies

The Environmental Protection Agency's mission is to protect human health and the environment. To accomplish this mission, they develop and enforce regulations, give grants, study environmental issues, sponsor partnerships, educate others, and publish information.

The U.S. Department of Agriculture provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

Agricultural Research Service (ARS) is USDA's principal in-house research agency. ARS leads America towards a better future through agricultural research and information.

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

The U.S. Geological Survey provides science about the natural hazards that threaten lives and livelihoods; the water, energy, minerals, and other natural resources we rely on; the health of our ecosystems and environment; and the impacts of climate and land-use change.

Private Sector

Clyme Health is dedicated to improving the lives of people with poorly understood chronic illnesses by applying the latest in data analytics and collaborative care. We are first focused on Lyme disease.

Galaxy Diagnostics is a One Health company that provides reliable results for flea and tick-borne pathogens, like Bartonella, Borrelia (Lyme Disease), and other flea- and tick-borne diseases through close partnerships with healthcare providers, veterinarians, and researchers.

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.

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.

Light Collective is a nonprofit on a mission to help peer support groups foster healthy human connections on the internet. We provide tools, resources, and training for patient peer support group leaders to practice collective self governance, negotiate fair partnerships, and foster good moderation + cyber hygiene practices.

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.

Veramarx Inc. is a patented immunoassay of ten inflammatory biomarkers that are measured upstream from the current two-tiered antibody method.

Appendix IV - Webinar Agenda

Public Webinar on LymeX: Bridging the Trust Gap
April 28, 2021, Noon to 1:00 pm Eastern time

Welcome and Introduction to LymeX Health+

Alex Wilson, LymeX Coordinator and IT Specialist, HHS

Special Address: Bridging the Trust Gap: Why We Need LymeX

Kristen Honey, PhD, PMP, Chief Data Scientist, Senior Advisor, HHS

Introduction of Speakers

Joel Gurin, President, Center for Open Data Enterprise (CODE)

Keynote Address: How Patients Are Contributing to Lyme Research

Lorraine Johnson, CEO, LymeDisease.org

Lightning Talk: Building Awareness and Momentum on Tick-borne Illness

Nevena Zubcevik, Chief Medical Officer, Invisible International

Lightning Talk: New Technologies to Improve the Patient Experience with Lyme

Lauren Pfeifer, VC and Technologist

Lightning Talk: A Patient-Centered Model for Evaluation and Care

Brian A. Fallon, MD, Director, Cohen Center for Health and Recovery from Tick-Borne Diseases at Columbia University

General Q&A

Webinar End