



Lyme Innovation Initiative and LymeX Innovation Accelerator

**Multi-Year Plan to Change the
Lyme Disease Status Quo**

**U.S. Department of Health and Human Services
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LYME

TICK-BORNE DISEASE
INNOVATION ACCELERATOR



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

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

LYME INNOVATION INITIATIVE AND LYME X INNOVATION ACCELERATOR MULTI-YEAR PLAN

INTRODUCTION

This report presents a multi-year plan to conquer Lyme disease through the HHS Lyme Innovation Initiative and its public-private partnership, the LymeX Innovation Accelerator (LymeX). The U.S. Department of Health and Human Services, under the auspices of the Office of the Assistant Secretary for Health, prepared this report to provide information on Lyme Innovation goals, activities, and measurable metrics of success. This multi-year plan for the HHS Lyme Innovation Initiative includes the LymeX partnership, which collectively will maximum impact to prevent and conquer Lyme disease and improve health outcomes.

All activities presented in this report align with *The National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People (VBD National Strategy)*¹. The *VBD National Strategy* provides the overarching interagency goals, strategic priorities, objectives, and subobjectives. OASH and its LymeX partnership have proactively aligned efforts to advance *VBD National Strategy* goals with a whole-of-government response to vector-borne diseases.

BACKGROUND

Lyme Disease

Centers for Disease Control and Prevention estimates that approximately 476,000 Americans are diagnosed and treated for Lyme disease each year². Tickborne disease more than doubled between 2004–2016³ and continues to increase⁴. Lyme disease accounted for 82% of all U.S. tickborne cases and 77% of all vector-borne diseases between 2004–2016⁵. Climate and habitat changes have accelerated the migration of ticks across the United States⁶. The true incidence of Lyme disease is unknown due in part to the lack of diagnostic technology for an active infection.

¹ <https://www.CDC.gov/VBD>

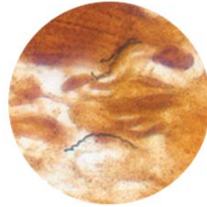
² <https://www.cdc.gov/lyme/datasurveillance/index.html>

³ <https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm>

⁴ https://www.cdc.gov/ncezid/dvbd/pdf/Brochure_National_Framework_VBDs-P.pdf

⁵ <https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm>

⁶ <https://www.cdc.gov/ncezid/what-we-do/climate-change-and-infectious-diseases/index.html>



~476,000

people estimated to be
diagnosed with Lyme disease
each year in the United States

Figure 1. Lyme bacteria. Image Source: CDC

Kay Hagan Tick Act

In 2019, Congress passed the Kay Hagan Tick Act (codified at 42 U.S.C. §§ 247b-23 and 300hh-32), signed into law as part of the [Further Consolidated Appropriations Act, 2020⁷](#).

The Act specified that “The [HHS] Secretary shall ensure the development and implementation of a national strategy to address vector-borne diseases, including tickborne diseases.”⁸ OASH and the CDC co-led the efforts to develop the VBD National Strategy, which was completed in collaboration with an interagency group of 17 divisions across civilian agencies and defense departments.

National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People

The VBD National Strategy identifies five, top-level goals for the Executive Branch.

- ***VBD National Strategy Goal 1:*** Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases
- ***VBD National Strategy Goal 2:*** Develop, evaluate, and improve tools, methods, and guidance to diagnose Vector-borne diseases and their pathogens
- ***VBD National Strategy Goal 3:*** Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases
- ***VBD National Strategy Goal 4:*** Develop and assess drugs and treatment strategies for vector-borne diseases
- ***VBD National Strategy Goal 5:*** Disseminate and implement public health tools, programs, and collaborations to prevent, detect, diagnose, and respond to vector-borne disease threats

⁷<https://www.congress.gov/116/bills/hr1865/BILLS-116hr1865enr.pdf>

⁸ 42 U.S.C. § 247b–23 (a)(1)(A)

Each goal has strategic priorities, objectives, and sub-objectives with accountability to identify the relevant federal agencies working to implement the objectives. The *VBD National Strategy* includes five goals, 19 strategic priorities, 43 objectives, and 124 sub-objectives.

HHS Lyme Innovation Initiative

The [HHS Lyme Innovation⁹](https://www.hhs.gov/ash/osm/innovationx/lyme-innovation/index.html) initiative, launched in 2018 and in OASH “[InnovationX¹⁰](https://www.hhs.gov/ash/osm/innovationx/index.html)” portfolio (formerly with the HHS Office of the Chief Technology Officer), is a broad umbrella of methods with innovation and partnership activities. HHS Lyme Innovation includes, but is not limited to

- [LymeX Innovation Accelerator¹¹](https://www.hhs.gov/ash/osm/innovationx/lyme-innovation/lymex/index.html) and [LymeX public-private Partnership¹²](https://lyme-x.org/) with the Steven & Alexandra Cohen Foundation, announced 2020
- [Health+™ \(pronounced “health plus”\) Lyme Disease Human-Centered Design¹³](https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf), launched in 2020, with patients at the center of creating Lyme Innovation solutions; Health+™ expanded in 2022 to include the [U.S. Digital Corps¹⁴](https://digitalcorps.gsa.gov/) technology talent and designers deployed to HHS
- [LymeX “ECHO” project¹⁵](https://www.darpa.mil/program/epigenetic-characterization-and-observation), announced 2021, which includes HHS collaboration with the Defense Advanced Research Projects Agency (DARPA), [Epigenetic CHaracterization and Observation Program¹⁶](https://www.darpa.mil/program/epigenetic-characterization-and-observation) to revolutionize Lyme disease diagnostics by harnessing the power of emerging technologies with epigenetics, methods of artificial intelligence (AI), and digital diagnostics
- [LymeX Diagnostics Prize¹⁷](https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=overview), HHS entered into an Interagency Agreement with the NASA Center of Excellence for Collaborative Innovation (CoECI), which provided innovation expertise and guidance to help design a multi-year, multi-phased [LymeX Diagnostics Prize¹⁸](https://www.challenge.gov/?challenge=lymex-diagnostics-prize) launched in 2022
- [LymeX Education and Awareness “Healthathon”¹⁹](https://www.challenge.gov/?challenge=lymex-education-and-awareness-healthathon) innovation sprints, [tech sprints²⁰](https://lymex.crowdcity.com/), and agile sprints to create solutions *with* (not for) patients, advocates, caregivers, frontline clinicians, researchers, policy makers, industry leaders, community organizers, technologists, and diverse participants from all sectors.

⁹ <https://www.hhs.gov/ash/osm/innovationx/lyme-innovation/index.html>

¹⁰ <https://www.hhs.gov/ash/osm/innovationx/index.html>

¹¹ <https://www.hhs.gov/ash/osm/innovationx/lyme-innovation/lymex/index.html>

¹² <https://lyme-x.org/>

¹³ <https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf>

¹⁴ <https://digitalcorps.gsa.gov/>

¹⁵ <https://www.hhs.gov/blog/2021/12/27/launching-partnerships-and-lymex-echo-to-drive-diagnostics-innovation-for-lyme-disease.html>

¹⁶ <https://www.darpa.mil/program/epigenetic-characterization-and-observation>

¹⁷ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=overview>

¹⁸ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize>

¹⁹ <https://www.challenge.gov/?challenge=lymex-education-and-awareness-healthathon> and <https://lymex.crowdcity.com/>

²⁰ <https://healthdata.gov/stories/s/jbsf-em78>

The HHS Lyme Innovation Initiative and LymeX Partnership aim to (1) signal HHS interest in Lyme disease; (2) encourage all sectors and U.S. markets to engage in Lyme disease; (3) expand the solution space and engage new solvers by reaching wide communities of experts who may have solutions but have not yet applied their expertise to Lyme disease; (4) accelerate the pace of Lyme disease science and diagnostic technologies; (5) raise public awareness of Lyme disease and to improve disease prevention; (6) harness the power of the crowd through crowdsourcing, citizen science, and “open” methods to create solutions using creation best practices²¹.



Figure 2. Blacklegged Tick. Image Source: CDC

Activities within the HHS Lyme Innovation Initiative and LymeX Partnership augment and complement—but do not in any way replace—federally funded science and vector-borne disease initiatives by other offices. For example, HHS Lyme Innovation Initiative and the LymeX Partnership augment and complement the

- *NIH Strategic Plan for Tickborne Disease Research*²² (NIH, October 2019);
- *A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans*²³ (CDC, September 2020); and
- *The National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People*²⁴ (HHS, 2024).

When aligned to the 2024 *VBD National Strategy*, HHS Lyme Innovation and its LymeX partnerships advance three of the five interagency goals. All Lyme Innovation and LymeX efforts involve regular coordination and collaboration with CDC, the National Institutes of Health, the Food and Drug Administration, and other leading agencies implementing *VBD National Strategy* goals.

²¹ <https://www.opengovpartnership.org/ogp-participation-co-creation-standards/>

²² <https://www.niaid.nih.gov/sites/default/files/NIH-Strategic-Plan-Tickborne-Disease-Research-2019.pdf>

²³ <https://www.cdc.gov/ncezid/dvbd/framework.html>

²⁴ <https://www.hhs.gov/ash/osm/innovationx/vector-borne-disease-national-strategy/index.html>

- **VBD National Strategy Goal 2:** Develop, evaluate, and improve tools, methods, and guidance to diagnose vector-borne diseases and their pathogens
- **VBD National Strategy Goal 3:** Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases
- **VBD National Strategy Goal 5:** Disseminate and implement public health tools, programs, and collaborations to prevent, detect, diagnose, and respond to vector-borne disease threats

INNOVATION IN RESPONSE TO CONGRESSIONAL DIRECTION

When the Kay Hagan Tick Act became law in 2019, HHS aligned its nascent Lyme Innovation portfolio to Congressional direction on Lyme disease. Since 2020, HHS focused the LymeX Partnership around three focus areas with the tagline “Together, Redefining the Lyme Status Quo.”

- **LymeX Focus Area #1: Patient-Centered Innovations**—With Lyme disease patients at the core of the HHS innovation process, use human-centered design and human-centered innovation to identify, develop, and implement solutions.
- **LymeX Focus Area #2: Education and Awareness**—Deliver innovative health education that brings tickborne-disease prevention to light using open innovation methods like crowdsourcing, citizen science, prize competitions, public-facing events, and agile sprints.
- **LymeX Focus Area #3: Next-Generation Diagnostics**—Design and execute a \$10-million-dollar [LymeX Diagnostics Prize²⁵](https://www.challenge.gov/?challenge=lymex-diagnostics-prize), which is a multi-year, multi-phase series of prize competitions aimed at accelerating the development and submission for FDA review of Lyme disease diagnostics funded by HHS’ LymeX partner, the Steven & Alexandra Cohen Foundation.

All three LymeX focus areas include Lyme disease patients and community at every step of the HHS innovation process. The success of the HHS Lyme Innovation initiative and its LymeX partnerships rests on regular community engagements, where Lyme disease patients and advocates meaningfully drive discussions and help identify priorities for future action. As such, this Lyme Innovation and LymeX Multi-Year Plan is subject to change, based on public engagements and feedback to HHS.

²⁵ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize>

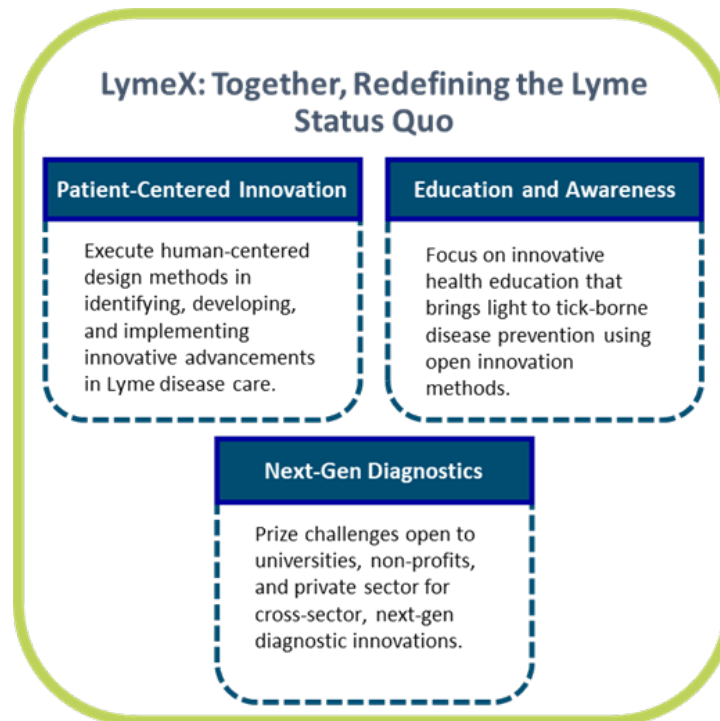


Figure 3. LymeX tagline and three focus areas. Image Source: HHS OASH

Evolving Priorities in Response to Public Co-Creation

Co-creation may be defined as the process of designing a product or service in which input from all partners plays a central role. The [Open Government Partnership \(OGP\)](https://www.opengovpartnership.org/)²⁶, is a global organization that includes participants at national and local levels, including the United States. Research based on OGP data over the last ten years shows that co-creation processes lead to well-designed and more ambitious commitments. Co-creation allows and requires public participation, which improves the quality of services based on the needs of and insights from those most affected by an issue.

The HHS Lyme Innovation initiative and its LymeX partnership remain committed to government transparency, accountability, and responsiveness to U.S. citizens, as originally committed in the [Fourth Open Government National Action Plan for the United States of America](https://open.usa.gov/assets/files/NAP4-fourth-open-government-national-action-plan.pdf)²⁷.

²⁶ <https://www.opengovpartnership.org/>

²⁷ <https://open.usa.gov/assets/files/NAP4-fourth-open-government-national-action-plan.pdf>

“Data-Driven Innovation for Lyme and Tickborne Diseases. In response to online petitions and public demand that the Federal Government prioritize Lyme and tickborne diseases, the HHS Office of the Chief Technology Officer (CTO) will launch a new public-private collaborative—a Lyme and Tickborne Disease Innovation Accelerator. Lyme disease sickens more than 300,000 Americans every year and is the fastest-growing vector-borne disease in the United States, which drains tens of billions of dollars from the economy. To address this multi-faceted challenge, HHS will host a series of “Lyme Innovation” listening sessions, roundtables, and events designed to harness the power of the crowd and leverage emerging technologies in order to co-create solutions with patients and practitioners as partners.”

- The Open Government Partnership (February 2019)²⁸

Below is the HHS Lyme Innovation and LymeX Multi-Year Plan by fiscal year, beginning with 2020. This Lyme Innovation and LymeX Multi-Year Plan is subject to change, based on public engagements and feedback to HHS.

HHS LYME INNOVATION MULTI-YEAR PLAN

FISCAL YEAR 2020: HHS launched the LymeX Partnership, following a year of engaging patients and diverse communities through a patient-centered lens to deliver innovative Lyme disease education materials, patient perspective reports, and crowdsourcing platforms.

In early 2020, LymeX launched its Health+™ Lyme disease cycle with human-centered design. Starting from the viewpoint of patient-centered innovation, OASH completed almost 700 hours of interviews, listening sessions, and workshops to better understand the journeys of patients navigating Lyme disease diagnosis and treatment. Its report, published in June 2020, identified four “opportunity areas” that the Lyme community self-identified to most benefit patients today.

LymeX ran a LymeX Education and Awareness “Healthathon” (innovation sprint) in April 2020 to crowdsource solutions from the public. Like a hackathon, yet a health-focused sprint, the Healthathon called on the public to create educational materials and raise awareness about tickborne-disease prevention and science. Diverse participants, including two winning K-12 innovators, contributed Lyme Innovation solutions. The LymeX Education and Awareness Healthathon resulted in five winners who HHS featured at a virtual event, on YouTube, and in social media.

HHS and the Steven & Alexandra Cohen Foundation publicly announced their \$25 million public-private partnership and the LymeX Innovation Accelerator in October 2020.

²⁸ <https://open.usa.gov/assets/files/NAP4-fourth-open-government-national-action-plan.pdf>

Fiscal Year 2020 Activity	LymeX Focus Area	Strategy Alignment	Measurable Metrics of Success, Deliverables, Outcomes
LymeX Partnership between HHS and the Steven & Alexandra Cohen Foundation	All	All	Established the world’s largest public-private partnership for Lyme disease with \$25M commitment from the Steven & Alexandra Cohen Foundation.
Health+™ Lyme Disease Human-Centered Design	Patient-Centered Innovation	Goal 5	Initiated Health+™ with 700 hours of interviews and research to validate the journeys of Lyme patients and identify “opportunity areas” that patients and practitioners want to see.
LymeX Administration, Communications, Software	All	Goal 2	Procured a crowdsourcing platform for digital innovation in Lyme disease.

FY 2020 Deliverables and Work Products

- HHS and Steven & Alexandra Cohen Foundation LymeX Memorandum of Understanding
- LymeX website launched, [Lyme-X.org](https://www.lyme-x.org/)²⁹
- LymeX Open Innovation ecosystem launched, [LymeX.crowdicity.com](https://lymex.crowdicity.com/)³⁰

FISCAL YEAR 2021: LymeX focused on human-centered design and diagnostics innovation, including planning the LymeX Diagnostic Prize and collaborations for a Lyme epigenetic biomarker signature.

In April 2021, HHS and its LymeX partner, the Steven & Alexandra Cohen Foundation, co-hosted a [LymeX Roundtable: Bridging the Trust Gap](#)³¹ to collaborate on inclusive strategies for patient-driven research and patient-driven innovation. Public input to HHS emphasized the need for improved Lyme diagnostics and data-driven solutions, including information from patient registries.

In response to public requests for new diagnostics, LymeX collaborated with the Defense Advanced Research Projects Agency (DARPA). The DARPA [Epigenetic CHaracterization and Observation \(ECHO\)](#)³² program focused on the rapid detection of any threat, anytime, anywhere by using a new diagnostic landscape, the epigenome. This “LymeX ECHO” partnership applied DARPA’s ECHO technology to the evaluation of samples in existing Lyme disease sample biorepositories (“biobanks”) to find unique “fingerprints” to characterize the disease. This joint research approach holds promise for understanding disease states, including patients with enduring symptoms after antibiotic treatment

²⁹ <https://www.lyme-x.org/>

³⁰ <https://lymex.crowdicity.com/>

³¹ <http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf>

³² <https://www.darpa.mil/program/epigenetic-characterization-and-observation>

where no definitive diagnostics exist today. Johns Hopkins University provided LymeX ECHO with samples from the [Studies of Lyme Disease Immunology and Clinical Events \(SLICE\)](#)³³ biorepository. In February 2021, HHS issued a request for information (RFI) to obtain information from the public on the state of science and technology accelerating innovation in diagnostic testing for Lyme disease.

LymeX also collaborated with the [NASA Center of Excellence for Collaborative Innovation \(CoECI\)](#)³⁴ to design a multi-year, multi-phased LymeX Diagnostics Prize. It will move the next generation of diagnostics that detect Lyme disease infections in people toward FDA review.

Fiscal Year 2021 Activity	LymeX Focus Area	Strategy Alignment	Measurable Metrics of Success, Deliverables, Outcomes
HHS Request for Information (RFI): Accelerating Innovation in Diagnostic Testing for Lyme Disease	Next-Gen Diagnostics	Goal 2	HHS received 32 individual responses on the state of science and emerging technologies for the diagnosis of Lyme disease in preparation for the LymeX Diagnostics Prize competition.
Health+™ Lyme Disease Human-Centered Design	Patient-Centered Innovation	Goal 5	Completed Health+™ with 700 hours of interviews and research with opportunity areas for HHS Lyme Innovation. Findings published in a report ³⁵ .
LymeX Webinar: Health+™ Human-Centered Design	Patient-Centered Innovation	Goal 5	HHS and the Steven & Alexandra Cohen Foundation hosted a webinar on Health+™ and the Human-Centered Design approach to facilitate patient-powered innovations for Lyme disease.
LymeX Roundtable Webinar: Bridging the Trust Gap	Patient-Centered Innovation	Goal 5	Created inclusive strategies for patient-driven research and innovation with 70 participants and 1500 viewers. Findings published in report ³⁶ .
LymeX Education and Awareness Healthathon	Education and Awareness	Goal 2	Crowdsourced winning solutions with over 60 ideas created and over 70,000 page views that raised awareness for Lyme and tick-bite prevention.
LymeX Diagnostics Prize	Next-Gen Diagnostics	Goal 2	Completed market research and developed implementation plan.

³³ <http://www.slicestudies.org/>

³⁴ <https://www.nasa.gov/coeci/>

³⁵ <https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf>

³⁶ <http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf>

LymeX ECHO Partnerships and Base Contract	Next-Gen Diagnostics	Goal 2	Procured well-characterized samples from the Johns Hopkins SLICE Biobank and Lyme biorepositories for DARPA ECHO analysts.
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FY 2021 Deliverables and Work Products

- [LymeX.crowdcity.com](https://lymex.crowdcity.com)³⁷ for LymeX Open Innovation crowdsourcing with Healthathon winners
- [Lyme-X.org](https://lyme-x.org/)³⁸ website updates
- [HHS RFI: Accelerating Innovation in Diagnostic Testing for Lyme Disease](https://www.federalregister.gov/documents/2021/02/11/2021-02796/request-for-information-rfi-accelerating-innovation-in-diagnostic-testing-for-lyme-disease)³⁹ (February 2021)
- [Health+™ Lyme Disease Human Centered Design Report](https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf)⁴⁰ (April 2021)
- [LymeX Roundtable Webinar: Bridging the Trust Gap](https://www.youtube.com/watch?v=awzNEKMvac4)⁴¹, HHS Webinar (April 2021)
- [LymeX Webinar: Health+™ Human-Centered Design](https://www.youtube.com/watch?v=qWe9Zv-gV6s)⁴², HHS Webinar (May 2021)
- [LymeX Roundtable: Bridging the Trust Gap Summary Report](http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf)⁴³ (June 2021)
- HHS and DARPA LymeX ECHO Memorandum of Understanding (August 2021)
- HHS blog for transparency with the public, [Launching Partnerships and “LymeX ECHO” to Drive Diagnostics Innovation for Lyme Disease](https://www.hhs.gov/blog/2021/12/27/launching-partnerships-and-lymex-echo-to-drive-diagnostics-innovation-for-lyme-disease.html)⁴⁴ (December 2021)

FISCAL YEAR 2022: \$10 Million LymeX Diagnostics Prize advances solutions toward FDA review, while continuing to bridge the trust gap with a series of patient-centered events.

At the beginning of fiscal year 2022, HHS hosted a LymeX Research Workshop entitled “Advancing Patient-Driven Research for Lyme Disease.” Hands-on breakout groups included patients, caregivers, advocates, researchers, government scientists, and policy makers working on vector-borne disease.

- LymeX Workshop Breakout 1: Improving Patient Outcomes
- LymeX Workshop Breakout 2: Ensuring Health Equity in Diagnosis, Prevention, and Control
- LymeX Workshop Breakout 3: Advancing Treatment of Tickborne Diseases
- LymeX Workshop Breakout 4: Data for Lyme Innovation

Based on input on public priorities, HHS designed and launched the [LymeX Diagnostics Prize Phase 1 on Challenge.gov](https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes)⁴⁵ to usher improved diagnostics to market. Phase 1 called for scientific, technical, and

³⁷ <https://lymex.crowdcity.com/>

³⁸ <https://lyme-x.org/>

³⁹ <https://www.federalregister.gov/documents/2021/02/11/2021-02796/request-for-information-rfi-accelerating-innovation-in-diagnostic-testing-for-lyme-disease>

⁴⁰ <https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf>

⁴¹ <https://www.youtube.com/watch?v=awzNEKMvac4>

⁴² <https://www.youtube.com/watch?v=qWe9Zv-gV6s>

⁴³ <http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf>

⁴⁴ <https://www.hhs.gov/blog/2021/12/27/launching-partnerships-and-lymex-echo-to-drive-diagnostics-innovation-for-lyme-disease.html>

⁴⁵ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes>

clinical experts to submit innovative methods for detecting active Lyme disease infections in people. In August 2021 HHS received 52 diagnostic submissions from industry, academia, and cross-sector teams. A panel of diverse judges scored submissions to select ten winners. Each winner received \$100,000. Winners were invited to participate in the LymeX Diagnostics Prize Phase 2.

Also in 2022, HHS sponsored the [2022 Health Equity DataJam⁴⁶](#), where patients transform raw data into actionable insights and digital tools to bridge disparities of health, including those exacerbated by barriers to care, Long COVID (and associated conditions), cancer, infection-associated chronic illnesses and kidney and Lyme disease, to ensure equitable access and wellness for all. The winning submission developed a Lyme symptom and treatment tracking app with database mapping to disability data sets, environmental data, pollutants triggers, and other variables that affect those living with chronic illness. This digital tool aids Lyme disease patients and practitioners, as it is used in clinics today. The DataJam demonstrated the enormous potential for HHS Lyme Innovation efforts to see effective and commercially viable products for the public good.

HHS held a LymeX Research Workshop in FY 2022, where individuals in breakout groups discussed: supporting research to advance treatment; ensuring health equity in diagnosis, prevention, and control; expanding data sources and data use, including privacy and governance; improving patient outcomes.

To implement workshop ideas, HHS recruited and on-boarded digital fellows, including a designer from the U.S. Digital Corps⁴⁷ to improve the way people in America are served by their government. A member of the Digital Corps helps deliver on Human Centered Design projects for the Lyme Innovation Initiative and LymeX Innovation Accelerator.

Fiscal Year 2022 Activity	LymeX Focus Area	Strategy Alignment	Measurable Metrics of Success, Deliverables, Outcomes
LymeX Research Workshop: Advancing Patient-Driven Research for Lyme Disease	Patient-Centered Innovation	Goal 5	At this workshop, approximately 50 participants, including 17 Lyme patients and advocates, shared input on patient-driven research.
Health Datapalooza with Lyme Innovation and 2022 Health Equity DataJam	Education, Awareness, Public Health Tools	Goal 2	Conference and DataJam incentivized industry, academia, and non-government organizations to transform HHS open data into digital tools with the 2022 winning submission a Lyme symptom tracking tool for care management.

⁴⁶ <https://healthdata.gov/stories/s/Health-Equity-DataJam-Homepage-2022/nzqx-ib2f/>

⁴⁷ <https://digitalcorps.gsa.gov/>

LymeX Diagnostics Prize pre-launch announcement	Next-Gen Diagnostics	Goal 2	LymeX open call for letters of intent through Challenge.gov, which generated ten letters of intent from U.S. researchers advancing the next generation of diagnostics for Lyme disease.
LymeX Diagnostics Prize	Next-Gen Diagnostics	Goal 2	LymeX designed, delivered, and judged Phase 1 to identify ten winners. LymeX conducted market research and designed Phase 2.
\$1M Cash Prizes to LymeX Phase 1 Winners	Next-Gen Diagnostics	Goal 2	Awarded one-million-dollar prize purse, evenly split with \$100,000 to each Phase 1 winner.

FY 2022 Deliverables and Work Products

- [Lyme-X.org⁴⁸](https://lyme-x.org/) website updates
- [LymeXDiagnosicsPrize.com⁴⁹](https://www.lymexdiagnosticsprize.com/) website launch
- [LymeX News⁵⁰](https://www.lyme-x.org/reports/) with chronological list of HHS Lyme Innovation events, reports, and deliverables
- [Lyme Innovation: 2022 Health Equity DataJam⁵¹](https://healthdata.gov/stories/s/9q39-eeqb) with HHS open data (February – May 2022)
- [LymeX Diagnostics Prize on Challenge.gov⁵²](https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes), official prize rules
 - Pre-launch announcement with call for LymeX Letters of Intent (open January–March 2022)
 - LymeX Diagnostics Prize Phase 1 (open May–August 2022)
 - LymeX Diagnostics Prize Phase 2 market research

FISCAL YEAR 2023: LymeX delivered Phase 2 of the LymeX Diagnostics Prize and novel epigenetic biomarker signatures, while also engaging diverse partners to outline future priorities.

The LymeX ECHO team validated Lyme disease samples using DARPA’s ECHO technology with DARPA-funded performers advancing the science and developing unique biomarker signatures from epigenetics for early-stage Lyme disease. HHS launched and ran the LymeX Diagnostics Prize Phase 2, which was the second stage in a multi-stage prize competition to further develop and prototype innovative diagnostics. Phase 2 had a \$2 million prize purse and included a six-month LymeX Virtual Accelerator.

⁴⁸ <https://lyme-x.org/>

⁴⁹ <https://www.lymexdiagnosticsprize.com/>

⁵⁰ <https://www.lyme-x.org/reports/>

⁵¹ <https://healthdata.gov/stories/s/9q39-eeqb>

⁵² <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes>

In February 2023, HHS announced a three-month Lyme Innovation technology sprint, as part of the [2023 Health Equity DataJam⁵³](#), for the public to transform HHS Open Data on HealthData.gov⁵⁴ into digital solutions for Lyme disease. It incentivized data-driven, patient-centered innovation for tickborne diseases. This momentum and public interest led HHS to host a “Lyme Innovation Co-Creation Workshop” in June 2023 for two-way public engagement in the open with transparency.

HHS’ LymeX partner, the Steven & Alexandra Cohen Foundation, with CDC, funded the National Academies of Sciences, Engineering, and Medicine (National Academies) to host a two-day workshop in June 2023. This workshop “Toward a Common Research Agenda in Infection-Associated Chronic Illnesses” examined common, overlapping clinical and biological factors with Lyme disease; Long COVID; Myalgic Encephalomyelitis, Chronic Fatigue Syndrome (also known as ME/CFS); and other chronic conditions. It included Lyme disease advocates and featured patients with chronic symptoms following infection by bacteria causing Lyme disease⁵⁵.

Fiscal Year 2023 Activity	LymeX Focus Area	Strategy Alignment	Measurable Metrics of Success, Deliverables, Outcomes
LymeX ECHO with DARPA	Next-Gen Diagnostics	Goal 2	Continued HHS-DARPA interagency agreement to develop diagnostics for Lyme disease from epigenetics.
LymeX Diagnostics Prize Phase 2	Next-Gen Diagnostics	Goal 2	Ten winning teams participated in a six-month LymeX Virtual Accelerator for mentoring, networking, and resourcing.
Health Datapalooza featuring Lyme Innovation with 2023 Health Equity DataJam	Education, Awareness, Public Health Tools	Goal 2	2023 conference and DataJam incentivized industry, academia, and non-government organizations to transform HHS open data into Lyme disease digital tools; submissions producing online resources and actionable insights for complex, chronic conditions.
Lyme Innovation Co-Creation Workshop	Patient-Centered Innovation	Goal 5	Interactive workshop to connect partners from all sectors to advance the Lyme disease field with patients at the core of the innovation process.
Lyme “Infection-Associated Chronic Illnesses” Events	Patient-Centered Innovation	Goal 5	LymeX partner and the National Academies hosted a two-day workshop on Lyme disease, Long COVID, ME/CFS, and chronic conditions.

⁵³ <https://healthdata.gov/stories/s/jbsf-em78>

⁵⁴ <https://healthdata.gov>

⁵⁵ <https://www.cdc.gov/ncezid/what-we-do/our-topics/chronic-symptoms.html>

FY 2023 Deliverables and Work Products

- [Lyme-X.org⁵⁶](https://lyme-x.org/) website updates
- [LymeX Diagnostics Prize.com⁵⁷](https://www.lymexdiagnosticsprize.com/) website updates
- [Lyme Innovation: 2023 Health Equity DataJam⁵⁸](https://healthdata.gov/stories/s/jbsf-em78) with HHS open data (February–May 2023)
- [LymeX Diagnostics Prize on Challenge.gov⁵⁹](https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes), official prize rules
 - LymeX Diagnostics Prize Phase 2 (open January–October 2023)
 - LymeX Diagnostics Prize Phase 3 market research
- [Lyme Innovation Co-Creation Workshop⁶⁰](https://www.eventbrite.com/e/lyme-innovation-co-creation-workshop-tickets-647129069467), HHS virtual event (June 2023)

FISCAL YEAR 2024: HHS continues with the LymeX Diagnostics Prize while advancing collaborative science and innovation for Lyme-infection-associated chronic illnesses.

HHS awarded \$2 million in cash prizes to winners of the LymeX Diagnostics Prize Phase 2. The LymeX Partnership anticipates designing and running the LymeX Diagnostics Prize Phase 3, contingent on available funding, to incentivize commercialization of technologies emerging from the LymeX Virtual Accelerator. The LymeX Diagnostics Prize Phase 3 will include preparing entrants for eventual submission to FDA for review of their diagnostic tool to detect active infection of Lyme disease-causing bacteria in humans.

In collaboration with our LymeX partner and the National Academies, the HHS Lyme Innovation Initiative is exploring common, overlapping clinical and biological factors across persistent Lyme disease; Long COVID; myalgic encephalomyelitis, chronic fatigue syndrome (ME/CFS); and multiple sclerosis⁶¹.

Fiscal Year 2024 Activity	LymeX Focus Area	Strategy Alignment	Expected Measurable Metrics of Success, Deliverables, Outcomes
\$2M Cash Prizes to LymeX Phase 2 Winners	Next-Gen Diagnostics	Goal 2	HHS to award \$2 million in prizes in early 2024.
LymeX Diagnostics Prize Phase 3	Next-Gen Diagnostics	Goal 2	LymeX team develop and launch Phase 3 of the LymeX Diagnostics Prize competition.

⁵⁶ <https://lyme-x.org/>

⁵⁷ <https://www.lymexdiagnosticsprize.com/>

⁵⁸ <https://healthdata.gov/stories/s/jbsf-em78>

⁵⁹ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes>

⁶⁰ <https://www.eventbrite.com/e/lyme-innovation-co-creation-workshop-tickets-647129069467>

⁶¹ <https://www.nationalacademies.org/our-work/toward-a-common-research-agenda-in-infection-associated-chronic-illnesses-a-workshop-to-examine-common-overlapping-clinical-and-biological-factors>

HHS Open Data, HealthData.gov ⁶² for Lyme Innovation	Education and Awareness	Goal 2	HHS and the public harness the power of open data, technology sprints, innovation sprints, and the creativity of the public to develop Lyme Innovation solutions.
Lyme-Infection-Associated Chronic Illnesses: Science Study and Consensus Building	All	All	HHS and LymeX partner engage the National Academies on Lyme-infection-associated chronic illnesses and build understanding across diverse groups.
Lyme Innovation Human-Centered Design	Patient-Centered Innovation	All	Interactive workshops, events, agile sprints, webinars, and co-creation sessions with the public and Lyme disease patients at the core of the innovation process.

FY 2024 Expected Deliverables and Work Products

- Lyme-X.org and LymeXDiagnosticsPrize.com website updates
- LymeX Diagnostics Prize Phase 3 on Challenge.gov
- Lyme-Infection-Associated Chronic Illnesses Webinars and Workshops, convened by the National Academies with support from HHS and LymeX partner

FISCAL YEAR 2025: The HHS Lyme Innovation Initiative and LymeX Partnership will continue harnessing the power of collaboration, data-driven innovation, and emerging technologies for Lyme disease with continued attention on Lyme-infection-associated chronic illnesses and conditions.

The HHS Lyme Innovation Initiative and LymeX Partnership will continue providing an innovation pipeline, scientific guidance, and technical assistance for emerging technologies to detect Lyme disease in humans. Through the LymeX public-private partnership, the LymeX Diagnostics Prize anticipates awarding up to \$2.1 million in cash prizes to Phase 3 winners. A future LymeX Diagnostics Prize Phase 4 will likely be the final phase of this multi-year, grand-prize challenge. LymeX expects to conclude its competitions and pay cash prizes only if LymeX benchmarks are achieved—hence, will pay only for performance—when technologies are reviewed successfully and cleared by the FDA for Lyme disease diagnosis. Success will be measured by the number of improved diagnostic tests that become available in U.S. markets for Lyme disease.

The HHS Lyme Innovation Initiative will continue to learn from patients with Lyme-infection-associated chronic illnesses. HHS Lyme Innovation work could ensure that patients are more than the targets for new prevention, diagnostic, and treatment tools. Patients are the driving forces of innovation, and their lived experiences are the roadmap for Lyme Innovation.

⁶² <https://healthdata.gov/>

Fiscal Year 2025 Activity	LymeX Focus Area	Strategy Alignment	Expected Measurable Metrics of Success, Deliverables, Outcomes
Cash Prizes to LymeX Phase 3 Winners	Next-Gen Diagnostics	Goal 2	LymeX may award cash prizes to winners submitting Phase 3 solutions for FDA submission.
LymeX Diagnostics Prize Phase 4	Next-Gen Diagnostics	Goal 2	Develop, launch, and execute future phases of the innovation challenge.
HHS Open Data, HealthData.gov for Lyme Innovation	Education and Awareness	Goal 2	HHS and the public harness the power of open data, technology sprints, innovation sprints, and the creativity of the public to develop Lyme Innovation solutions.
Lyme-Infection-Associated Chronic Illnesses: Advance Consensus Understanding	All	All	HHS and LymeX partner continue engaging with the National Academies to synthesize science and build understanding on Lyme-infection-associated chronic illnesses.
Lyme Innovation Human-Centered Design	Patient-Centered Innovation	Goal 5	Interactive workshops, events, agile sprints, webinars, and creation sessions with the public and Lyme disease patients at the core of the innovation process.

FY 2025 Expected Deliverables and Work Products

- Lyme-X.org and LymeXDiagnosicsPrize.com website updates
- LymeX Diagnostics Prize Phase 4 on Challenge.gov
- LymeX partner plans to sponsor a Lyme-Infection-Associated Chronic Illnesses Summary Report written by the National Academies

CONCLUSIONS

The HHS Lyme Innovation Initiative and LymeX Partnership will continue in alignment with Congressional direction to prevent and conquer Lyme disease.

Today’s three focus areas of patient-centered innovation, education and awareness, and next-generation diagnostics will evolve as the science progresses and the Lyme landscape changes. For example, when improved diagnostics move to market, then new priorities may be added. Future priorities will be determined in collaboration with Lyme disease patients, advocates, caregivers, frontline clinicians, researchers, policy makers, industry leaders, community organizers, technologists, ethicists, and diverse participants from all sectors. Importantly, Lyme disease patients will remain at the center of the HHS Lyme Innovation process.

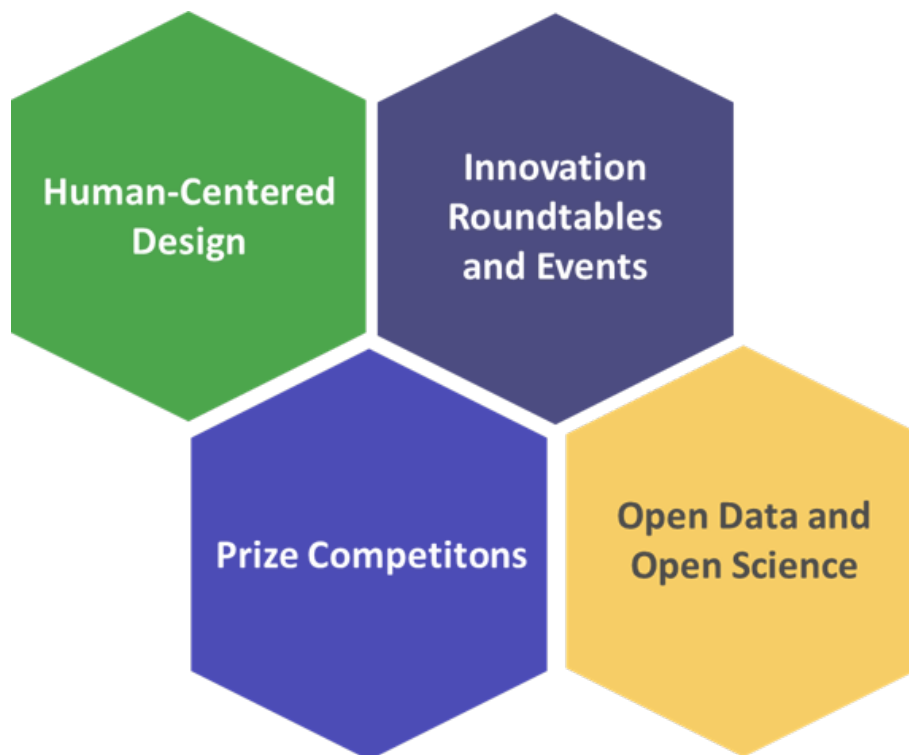


Figure 4. Lyme Innovation Methods. Image Source: HHS OASH

LOOKING FORWARD

Moving the needle on Lyme disease will require successful implementation of the *National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People* through continued collaboration, support, leadership, and excellence in innovation and implementation. Collaboration within and outside of the federal government is necessary to protect the nation and save lives. Government transparency is a priority for the HHS Lyme Innovation Initiative, which rests on a foundation of open science, open data, and open innovation. [Read and download the complete VBD National Strategy.](#)

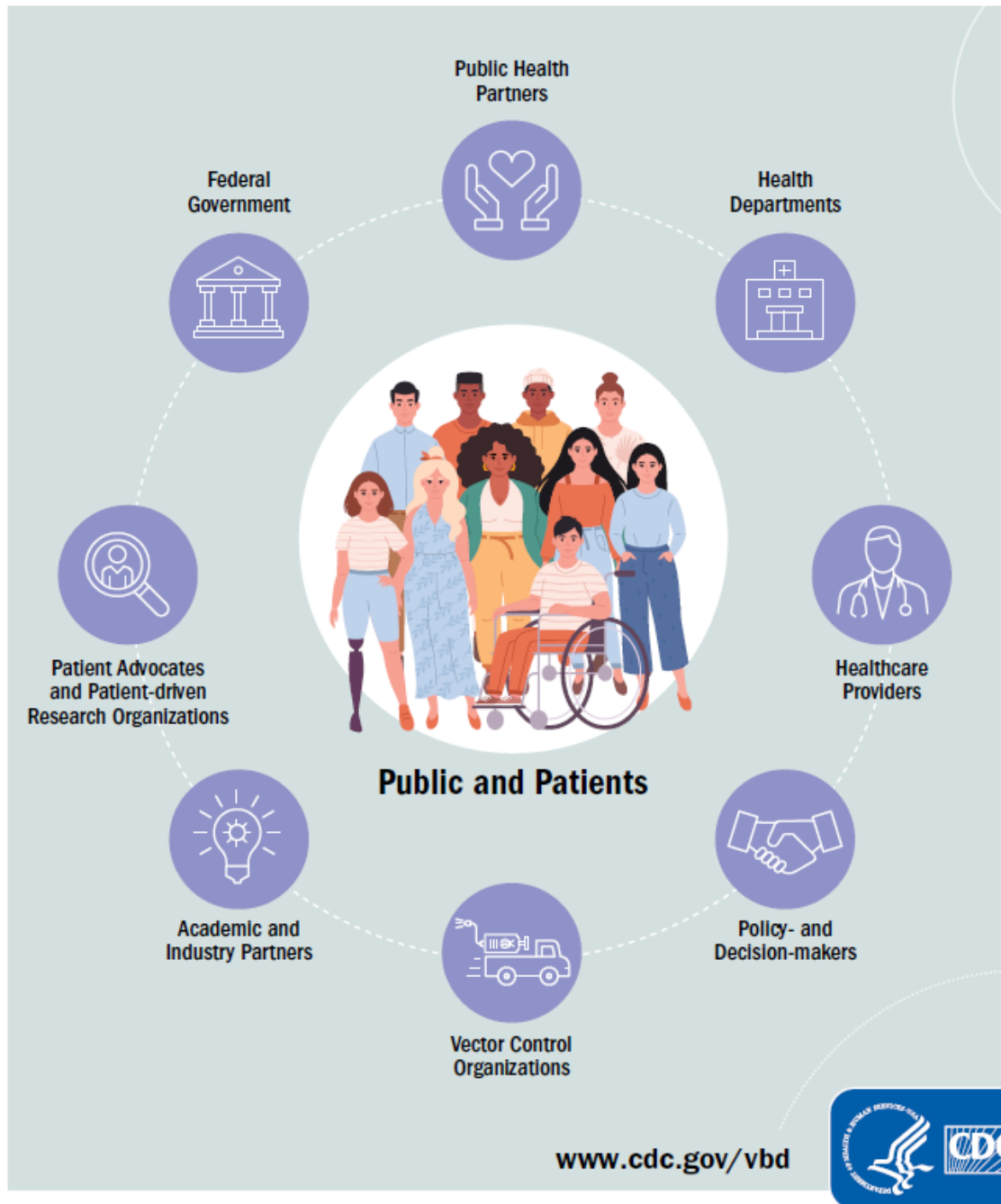


Figure 5. Looking forward. Image Source: CDC

Follow LymeX on X (formerly Twitter) at @Lyme_X or visit <https://www.lyme-x.org/>. Visit www.lymexdiagnosticsprize.com for more information on the LymeX Diagnostics Prize competition.

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