

Report to Congress: A Multi-Year Plan Outlining an Initiative to Conquer Lyme Disease

April 2024

A Report to the U.S. House Committee on Appropriations
as requested in the reports accompanying the Departments of Labor,
Health and Human Services, and Education, and Related Agencies
Appropriations Bills for fiscal years 2021 and 2022



U.S. Department of Health and Human Services
Office of the Secretary
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES LYME INNOVATION INITIATIVE AND LYME X INNOVATION ACCELERATOR MULTI-YEAR PLAN

INTRODUCTION AND CONGRESSIONAL REQUESTS

The Joint Explanatory Statements for the Fiscal Years 2021, 2022, and 2023 appropriations state the following regarding the HHS Lyme Innovation Initiative and Lyme X Innovation Accelerator:

"Lyme Disease—The Committee encourages the Office of the Secretary to sponsor initiatives to spur innovation leading to the development of more effective diagnostics for all stages of Lyme disease and for the development of novel treatments that will return patients to health and eradicate the disease, including innovation in tools and resources data, technology and scientist collaborations. The Committee is appreciative of the role of the Office of the Chief Technology Officer in promoting innovation to strengthen agency programs and foster public health solutions. The Committee urges the Secretary to coordinate and collaborate with the Operating Divisions, including NIH, CDC, and FDA, to apply data, technology, and human resources to overcome obstacles and develop solutions to effectively manage and eradicate Lyme disease. The Committee requests the Secretary submit within 180 days of enactment of this Act a multi-year plan outlining an initiative to conquer Lyme disease."

U.S. House Committee on Appropriations Report that accompanied the appropriation bill for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for fiscal year 2021, H.R. Rep. No. 116-450, at 210 (2020).

"Lyme X Innovation Accelerator—The Committee commends the Office of the Secretary and its Chief Technology Officer for the Lyme Innovation Initiative, launched November 2018, and the Lyme X Innovation Accelerator announced in October 2020. Lyme X is a \$25,000,000 public-private partnership between HHS and the Steven & Alexandra Cohen Foundation to accelerate innovation in prevention, diagnostics, and treatments for Lyme and other tickborne diseases. The Committee looks forward to receiving the multi-year plan outlining innovation initiatives for conquering Lyme disease, which is due in December 2021."

U.S. House Committee on Appropriations Report that accompanied the appropriation bill for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for fiscal year 2022, H.R. Rep. No. 117-96, at 236 (2021).

"Lyme X Innovation Accelerator—The Committee commends the Office of the Secretary and its Chief Technology Officer for the Lyme Innovation Initiative, launched November 2018, and the Lyme X Innovation Accelerator announced in October 2020. Lyme X is a \$25,000,000 public-private partnership between HHS and the Steven & Alexandra Cohen Foundation to accelerate innovation in prevention, diagnostics, and treatments for Lyme and other tickborne diseases."

U.S. House Committee on Appropriations Report that accompanied the appropriation bill for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for fiscal year 2023, H.R. Rep. No. 117-403, at 224-225 (2022).

This Report to Congress describes a multi-year plan to conquer Lyme disease through the HHS Lyme Innovation Initiative and 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 (OASH), 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 maximize impact to prevent and conquer Lyme disease and improve health outcomes.

BACKGROUND

Lyme Disease

Centers for Disease Control and Prevention estimates that approximately 476,000 Americans are diagnosed and treated for Lyme disease each year¹. Tickborne disease more than doubled between 2004–2016² and continues to increase³. Lyme disease accounted for 82% of all U.S. tickborne cases and 77% of all vector-borne diseases between 2004–2016⁴. Climate and habitat changes have accelerated the migration of ticks across the United States⁵. The true incidence of Lyme disease is unknown due in part to the lack of diagnostic technology for an active infection.

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, 2020](#)⁶.

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.”⁷ All activities presented in this report align with *The National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People* (the *VBD National Strategy*), which HHS published on February 6, 2024⁸. OASH and its LymeX partnerships have proactively aligned efforts to advance *VBD National Strategy* goals with a whole-of-government response to vector-borne diseases.

HHS Lyme Innovation Initiative

The [HHS Lyme Innovation](#)⁹ initiative, launched in 2018 and in OASH “[InnovationX](#)”¹⁰ 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

¹ <https://www.cdc.gov/lyme/datasurveillance/index.html>

² <https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm>

³ https://www.cdc.gov/nceid/dvbd/pdf/Brochure_National_Framework_VBDs-P.pdf

⁴ <https://www.cdc.gov/mmwr/volumes/67/wr/mm6717e1.htm>

⁵ <https://www.cdc.gov/nceid/what-we-do/climate-change-and-infectious-diseases/index.html>

⁶ <https://www.congress.gov/116/bills/hr1865/BILLS-116hr1865enr.pdf>

⁷ 42 U.S.C. § 247b–23 (a)(1)(A)

⁸ <https://www.hhs.gov/ash/osm/innovationx/vector-borne-disease-national-strategy/index.html>

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

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

- [LymeX Innovation Accelerator¹¹](#) and [LymeX public-private Partnership¹²](#) with the Steven & Alexandra Cohen Foundation, announced 2020
- [Health+™ \(pronounced “health plus”\) Lyme Disease Human-Centered Design¹³](#), launched in 2020, with patients at the center of creating Lyme Innovation solutions; Health+ expanded in 2022 to include the [U.S. Digital Corps¹⁴](#) technology talent and designers deployed to HHS
- [LymeX “ECHO” project¹⁵](#), announced 2021, which includes HHS collaboration with the Defense Advanced Research Projects Agency (DARPA), [Epigenetic CHaracterization and Observation Program¹⁶](#) 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](#), 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](#) launched in 2022
- [LymeX Education and Awareness “Healthathon”¹⁹](#) innovation sprints, [tech sprints²⁰](#), 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.

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.

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:

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>

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

- *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).

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 Prize](#)²⁵, 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.

Below is the HHS Lyme Innovation and LymeX Multi-Year Plan by fiscal year, beginning with 2020 because Congress first inquired about the department’s multi-year strategy that year. 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.

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>

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

Fiscal Year 2020 Activity	LymeX Focus Area	Measurable Metrics of Success, Deliverables, Outcomes
LymeX Partnership between HHS and the Steven & Alexandra Cohen Foundation	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	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	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/)²⁶
- LymeX Open Innovation ecosystem launched, [LymeX.crowdicity.com](https://lymex.crowdicity.com/)²⁷

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.

Fiscal Year 2021 Activity	LymeX Focus Area	Measurable Metrics of Success, Deliverables, Outcomes
HHS Request for Information (RFI): Accelerating Innovation in Diagnostic Testing for Lyme Disease	Next-Gen Diagnostics	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	Completed Health+™ with 700 hours of interviews and research with opportunity areas for HHS Lyme Innovation. Findings published in a report ²⁸ .
LymeX Webinar: Health+™ Human-Centered Design	Patient-Centered Innovation	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	Created inclusive strategies for patient-driven research and innovation with 70 participants and 1500 viewers. Findings published in report ²⁹ .
LymeX Education and Awareness Healthathon	Education and Awareness	Crowdsourced winning solutions with over 60 ideas created and over 70,000 page views that raised awareness for Lyme and tick-bite prevention.

²⁶ <https://www.lyme-x.org/>

²⁷ <https://lymex.crowdicity.com/>

²⁸ <https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf>

²⁹ <http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf>

LymeX Diagnostics Prize	Next-Gen Diagnostics	Completed market research and developed implementation plan.
LymeX ECHO Partnerships and Base Contract	Next-Gen Diagnostics	Procured well-characterized samples from the Johns Hopkins SLICE Biobank and Lyme biorepositories for DARPA ECHO analysts.

FY 2021 Deliverables and Work Products

- [LymeX.crowdacity.com](https://lymex.crowdacity.com/)³⁰ for LymeX Open Innovation crowdsourcing with Healthathon winners
- [Lyme-X.org](https://lyme-x.org/)³¹ 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)³² (February 2021)
- [Health+™ Lyme Disease Human Centered Design Report](https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf)³³ (April 2021)
- [LymeX Roundtable Webinar: Bridging the Trust Gap](https://www.youtube.com/watch?v=awzNEKMvac4)³⁴, HHS Webinar (April 2021)
- [LymeX Webinar: Health+™ Human-Centered Design](https://www.youtube.com/watch?v=qWe9Zv-gV6s)³⁵, HHS Webinar (May 2021)
- [LymeX Roundtable: Bridging the Trust Gap Summary Report](http://reports.opendataenterprise.org/CODE-LymeX-Roundtable-Report.pdf)³⁶ (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)³⁷ (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.

HHS hosted a LymeX Research Workshop entitled “Advancing Patient-Driven Research for Lyme Disease” at the beginning of the fiscal year. To implement workshop ideas, HHS recruited and on-boarded digital fellows, including a designer from the U.S. Digital Corps³⁸ to improve the way people in America are served by their government.

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)³⁹ to usher improved diagnostics to market. Each winner received \$100,000. HHS invited winners to participate in the LymeX Diagnostics Prize Phase 2.

HHS sponsored the [2022 Health Equity DataJam](https://healthdata.gov/stories/s/Health-Equity-DataJam-Homepage-2022/nzqx-jb2f/)⁴⁰. The winning submission developed a Lyme

³⁰ <https://lymex.crowdacity.com/>

³¹ <https://lyme-x.org/>

³² <https://www.federalregister.gov/documents/2021/02/11/2021-02796/request-for-information-rfi-accelerating-innovation-in-diagnostic-testing-for-lyme-disease>

³³ <https://www.hhs.gov/sites/default/files/healthplus-lyme-disease-hcd-report.pdf>

³⁴ <https://www.youtube.com/watch?v=awzNEKMvac4>

³⁵ <https://www.youtube.com/watch?v=qWe9Zv-gV6s>

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

³⁷ <https://www.hhs.gov/blog/2021/12/27/launching-partnerships-and-lymex-echo-to-drive-diagnostics-innovation-for-lyme-disease.html>

³⁸ <https://digitalcorps.gsa.gov/>

³⁹ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes>

⁴⁰ <https://healthdata.gov/stories/s/Health-Equity-DataJam-Homepage-2022/nzqx-jb2f/>

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 tool, now in clinical use, aids Lyme disease patients and practitioners. The DataJam accelerated the development, deployment, and adoption of commercially viable Lyme Innovation products for the public good.

Fiscal Year 2022 Activity	LymeX Focus Area	Measurable Metrics of Success, Deliverables, Outcomes
LymeX Research Workshop: Advancing Patient-Driven Research for Lyme Disease	Patient-Centered Innovation	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	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.
LymeX Diagnostics Prize pre-launch announcement	Next-Gen Diagnostics	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	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	Awarded one-million-dollar prize purse, evenly split with \$100,000 to each Phase 1 winner.

FY 2022 Deliverables and Work Products

- [Lyme-X.org⁴¹](https://lyme-x.org/) website updates
- [LymeX Diagnostics Prize.com⁴²](https://www.lymexdiagnosticsprize.com/) website launch
- [LymeX News⁴³](https://www.lyme-x.org/reports/) with chronological list of HHS Lyme Innovation events, reports, and deliverables
- [Lyme Innovation: 2022 Health Equity DataJam⁴⁴](https://healthdata.gov/stories/s/9q39-eeqb) with HHS open data (February – May 2022)
- [LymeX Diagnostics Prize on Challenge.gov⁴⁵](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

⁴¹ <https://lyme-x.org/>
⁴² <https://www.lymexdiagnosticsprize.com/>
⁴³ <https://www.lyme-x.org/reports/>
⁴⁴ <https://healthdata.gov/stories/s/9q39-eeqb>
⁴⁵ <https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes>

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.

In February 2023, HHS announced a three-month Lyme Innovation technology sprint, as part of the [2023 Health Equity DataJam](https://healthdata.gov/stories/s/jbsf-em78)⁴⁶, for the public to transform HHS Open Data on HealthData.gov⁴⁷ 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 disease⁴⁸.

Fiscal Year 2023 Activity	LymeX Focus Area	Measurable Metrics of Success, Deliverables, Outcomes
LymeX ECHO with DARPA	Next-Gen Diagnostics	Continued HHS-DARPA interagency agreement to develop diagnostics for Lyme disease from epigenetics.
LymeX Diagnostics Prize Phase 2	Next-Gen Diagnostics	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	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	Interactive workshop to connect partners from all sectors to advance the Lyme disease field with patients at the core of the innovation process.

⁴⁶ <https://healthdata.gov/stories/s/jbsf-em78>

⁴⁷ <https://healthdata.gov/>

⁴⁸ <https://www.cdc.gov/ncezid/what-we-do/our-topics/chronic-symptoms.html>

Lyme “Infection-Associated Chronic Illnesses” Events	Patient-Centered Innovation	LymeX partner and the National Academies hosted a two-day workshop on Lyme disease, Long COVID, ME/CFS, and chronic conditions.
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FY 2023 Deliverables and Work Products

- [Lyme-X.org](https://lyme-x.org/)⁴⁹ website updates
- [LymeX Diagnostics Prize.com](https://www.lymexdiagnosticsprize.com/)⁵⁰ website updates
- [Lyme Innovation: 2023 Health Equity DataJam](https://healthdata.gov/stories/s/jbsf-em78)⁵¹ with HHS open data (February–May 2023)
- [LymeX Diagnostics Prize on Challenge.gov](https://www.challenge.gov/?challenge=lymex-diagnostics-prize&tab=prizes)⁵², official prize rules
 - LymeX Diagnostics Prize Phase 2 (open January–October 2023)
 - LymeX Diagnostics Prize Phase 3 market research
- [Lyme Innovation Co-Creation Workshop](https://www.eventbrite.com/e/lyme-innovation-co-creation-workshop-tickets-647129069467)⁵³, 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 is awarding \$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 sclerosis⁵⁴. All HHS Lyme disease efforts will align to the *VBD National Strategy* priorities, while advancing its five goals for vector-borne diseases.

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

⁴⁹ <https://lyme-x.org/>

⁵⁰ <https://www.lymexdiagnosticsprize.com/>

⁵¹ <https://healthdata.gov/stories/s/jbsf-em78>

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

⁵³ <https://www.eventbrite.com/e/lyme-innovation-co-creation-workshop-tickets-647129069467>

⁵⁴ <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 ⁵⁵ for Lyme Innovation	Education and Awareness	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	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	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 LymeXDiagnosicsPrize.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.

Fiscal Year 2025 Activity	LymeX Focus Area	Expected Measurable Metrics of Success, Deliverables, Outcomes
Cash Prizes to LymeX Phase 3 Winners	Next-Gen Diagnostics	LymeX may award cash prizes to winners submitting Phase 3 solutions for FDA submission.
LymeX Diagnostics Prize Phase 4	Next-Gen Diagnostics	Develop, launch, and execute future phases of the innovation challenge.

⁵⁵ <https://healthdata.gov/>

HHS Open Data, HealthData.gov for Lyme Innovation	Education and Awareness	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	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	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 LymeXDiagnosticsPrize.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.

The HHS Lyme Innovation Initiative and LymeX Partnership will continue co-creation in three focus areas: (1) patient-centered innovation, (2) education and awareness, and (3) next-gen diagnostics. Co-creation may be defined as the process of designing a product or service in which input from all partners plays a central role. Co-creation allows and requires public participation, which improves the quality of services based on the needs of and insights from the public⁵⁶. Focus areas will evolve as the science progresses and landscape changes.

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 public-facing report, *HHS Lyme Innovation Initiative and LymeX Partnership Multi-Year Plan*⁵⁷ from HHS.gov.

⁵⁶ <https://www.opengovpartnership.org/documents/ogp-national-handbook-rules-and-guidance-for-participants-2022/>

⁵⁷ <https://www.hhs.gov/ash/osm/innovationx/lyme-innovation/index.html>