Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment

MEETING AGENDA

Research for Lyme Infection-Associated Chronic Illnesses Treatment: Broadening the Lens – Committee Meeting 2

WORKSHOP AGENDA

Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment

Thursday, July 11, 2024

Workshop Objectives:

- Describe the current state of Lyme IACI research for treatments and diagnostics to clarify barriers in development of new, effective therapeutic interventions;
- Explore recent advancements from other biomedical research fields with the potential to address these barriers by catalyzing scientific breakthroughs or translation of discoveries to treatments;
- Understand patient-defined priorities for research and discuss potential opportunities for engaging this perspective in developing a biomedical research agenda; and
- Discuss research strategies and infrastructure that could facilitate the application of innovations from other fields into the Lyme IACI research context.

DAY 1 – THURSDAY, JULY 11, 2024

CLOSED SESSION

9:00 AM Committee meets in closed session

OPEN SESSION

9:30 AM Welcome

KEN KESTER, Committee Chair
Former Vice President, Translational Medicine
IAVI
# Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment

## Meeting Agenda

### Opening Session: An Overview of Challenges in Lyme IACI Research

**Objectives**
- Understand Lyme IACI disease impact; and
- Present overview of current status of ongoing research for Lyme IACI.

**Framing Questions**
- What is the impact of Lyme IACI in the US and globally?
- What is the current evidence base toward understanding and developing treatments for Lyme IACI?
- What are key scientific or technical barriers in addressing challenges to develop new treatments?
- How are patient perspectives and input incorporated into prospective research studies?

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<tr>
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| 9:35 AM | **Patient Perspective: Impact of Lyme IACI**  
RHISA PARERA  
Patient  
Writer, Director, Producer  
*Your Labs Are Normal* |
| 9:45 AM | **Overview: Current Status and Challenges in Research for Lyme IACI Treatment**  
JOHN AUCOTT  
Director, Johns Hopkins Lyme Disease Clinical Research Center  
Associate Professor of Medicine  
Johns Hopkins University |
| 10:05 AM | **Building on Current Progress: Reflections from the HHS Tick-borne Diseases Working Group**  
C. BENJAMIN BEARD  
Deputy Division Director, Division of Vector-Borne Diseases  
Centers for Disease Control and Prevention |
| 10:15 AM | **Q&A** |
| 10:45 AM | **BREAK** |

### Session 1: Potential Commonalities Across Other Fields and Implications for Lyme IACI

**Objectives**
- Examine the commonalities between Lyme IACI and other diseases and potential shared mechanisms of pathology; and
- Evaluate the relative strength of evidence for the potential mechanisms of Lyme IACI pathology
- Discuss implications and unique considerations for Lyme IACI.

**Framing Questions**
- What similarities or differences exist between Lyme IACI and other IACI with neurologic, cognitive, or psychiatric symptoms?
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- What does the current evidence suggest about the biological plausibility of the neurologic, cognitive, and psychiatric symptoms of Lyme IACI being caused by different mechanisms of pathology?
- What factors should be considered in prospective studies that seek to identify whether there are inflammatory and/or autoimmune biomarkers associated with Lyme IACI?
- Is research on pathogen persistence from other IACI translatable to developing potential treatment for Lyme IACI?

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<tr>
<th>Time</th>
<th>Topic</th>
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<tr>
<td>11:00 PM</td>
<td>Autoimmune mechanisms of IACI</td>
<td>William Robinson</td>
<td>Stanford University</td>
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<td>11:10 PM</td>
<td>Inflammatory responses in IACI</td>
<td>Daniel Clauw</td>
<td>University of Michigan</td>
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<td>11:20 PM</td>
<td>Mechanisms of colonization and pathogenesis</td>
<td>John Leong</td>
<td>Tufts University</td>
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<td>11:30 PM</td>
<td>Elucidating pathophysiology: lessons from ME/CFS</td>
<td>Avindra Nath</td>
<td>National Institute of Neurological Disorders and Stroke, NIH</td>
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<td>11:40 PM</td>
<td>Discussion and Q&amp;A</td>
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<td>12:15 PM</td>
<td>LUNCH</td>
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SESSION 2: Advances in Diagnostics Research

Objectives
  - Explain the relationships between diagnostics research and research on Lyme IACI etiology and treatment;
  - Provide an overview of current approaches to diagnostics that may hold promise for Lyme IACI diagnosis;
  - Identify current challenges in advancing diagnostics to support development of Lyme IACI treatment and emerging technologies that may mitigate these challenges; and
  - Discuss opportunities for implementation of these emerging technologies and other mitigating factors.

Framing Questions
  - What are challenges in developing diagnostics for Lyme IACI?
  - How do these challenges impact development of treatments?
  - What scientific advances exist that may address these challenges?
  - What are barriers (technical and/or market forces) to implementing these technologies for Lyme IACI?
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1:00 PM  Current diagnostic approaches and emerging technologies
CHARLES CHIU
Professor of Laboratory Medicine and Medicine
University of California, San Francisco

1:10 PM  Challenges in diagnostics research
NANCY KLIWAS
Director, Institute for Neuro-Immune Medicine
Professor of Medicine
Nova Southeastern University

1:20 PM  Challenges in advancing new diagnostics development
RAYMOND DATTWYLER
Professor of Pathology, Microbiology and Immunology, Medicine, and Pediatrics
New York Medical College

1:30 PM  Challenges in regulatory considerations of new diagnostics
Elliott Cowan
Founder & Principal
Partners in Diagnostics

1:40 PM  Discussion and Q&A

SESSION 3: Strategies to Improve the Applicability of Research

Objectives
- Explore elements of study designs that enable collection of data from more inclusive patient samples;
- Discuss strategies to standardize research questions and outcome measures; and
- Assess the feasibility of implementing data sharing practices across Lyme IACI research studies;

Framing Questions
- What are key factors to model or consider in large or in-depth prospective studies designed to interrogate potential pathways to developing treatments for Lyme IACI?
- What challenges may have been encountered or can be anticipated in collecting and sharing data across different studies?

2:10 PM  Patient generated data
BETH JAWORSKI
Director of Participant Platforms
All of Us Research Program, National Institutes of Health
Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment
MEETING AGENDA

2:20 PM  Patient registries and biobanks for Lyme IACI  
LIZ HORN  
Principal Investigator  
Lyme Disease Biobank

2:30 PM  Platform trial designs toward standardization and quality across studies  
ROGER LEWIS  
Investigator, The Lundquist Institute  
Professor of Medicine  
University of California, Los Angeles

2:40 PM  Research trials network and data sharing  
RACHELE HENDRICKS-STURRUP  
Director, Real-World Evidence  
Duke-Margolis Institute for Health Policy

2:50 PM  Discussion and Q&A

3:20 PM  BREAK

SESSION 4:  Bridging Opportunities and Action

Session Objectives
- Identify additional barriers that restrict progress on Lyme IACI research;
- Consider how patient-defined research priorities and patient-reported outcomes can inform future research; and
- Discuss opportunities to advance translation of Lyme IACI research into development.

Framing Questions
- What mechanisms or processes are need to incorporate patient priorities into the research agenda in a more systematic way?
- How can barriers to the conduct of Lyme IACI research be overcome? Who needs to be involved in developing solutions to address those barriers?
- What opportunities already exist to advance Lyme IACI research toward the development of treatments and diagnostics, and how can those opportunities be better utilized?
- What would success look like if different stakeholders were able to align on research priorities for Lyme IACI treatment? Are there any examples of successful collaboration for Lyme IACI research?

3:30 PM  Panel Discussion: patient-defined priorities for research  
Patient-centered outcomes  
LORRAINE JOHNSON  
Chief Executive Officer  
LymeDisease.org
## Patient participation in research and data collection

**WENDY ADAMS**  
Research Grant Director  
Bay Area Lyme Foundation

**Bridging between funder and patient priorities**

**TIMOTHY SELLATI**  
Chief Scientific Officer  
Global Lyme Alliance

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| 4:00 PM | Funder perspective                 | **LEITH STATES**  
Chief Medical Officer  
Office of the Assistant Secretary for Health, HHS |
| 4:10 PM | Industry perspective               | **MATT TINDALL**  
Co-Founder, President and Chief Executive Officer  
FlightPath Biosciences |
| 4:20 PM | Regulatory perspective             | **STACIE HUDGENS**  
Chief Executive Officer  
Strategic Lead, Regulatory & Access  
Clinical Outcomes Solutions |
| 4:30 PM | Discussion and Q&A                 |                                                                            |
| 4:55 PM | Final Remarks                      | **KENT KESTER,** *Committee Chair*  
Former Vice President, Translational Medicine  
IAVI |
| 5:00 PM | ADJOURN DAY 1                      |                                                                            |
## DAY 2 – FRIDAY, JULY 12, 2024

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<tr>
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<td>ADJOURN MEETING</td>
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