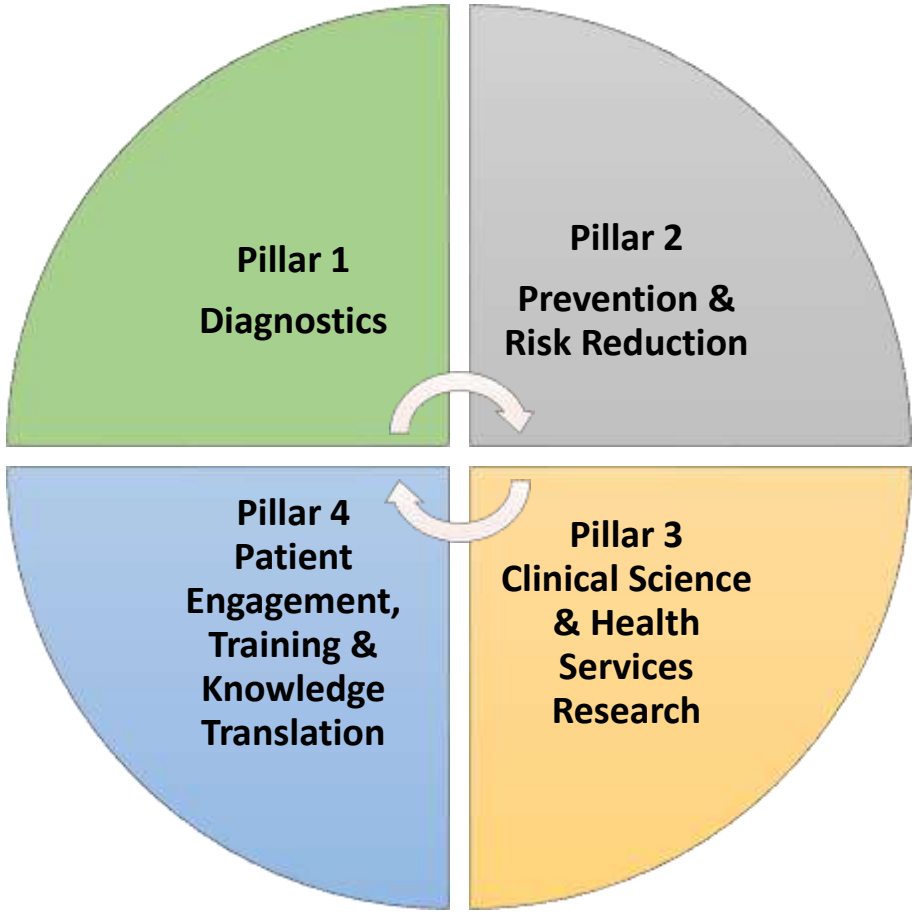
# Canadian Lyme Disease Research Network (CLyDRN)

CANADIAN LYME DISEASE
RESEARCH NETWORK

# CLyDRN Pillars



# Brief background

**Patient-Priority Led Project:**

- 7-step priority setting process framework developed in October 2019.
- Final step completed January 2021.

**Identified Top 3 Patient Priorities**:

- Lyme disease testing unreliable.
- Current testing modalities lack adequate sensitivity and specificity to accurately diagnosis Lyme disease.
- Two-tiered serological testing yields inconsistent results among patients that share similar tick exposure histories, clinical portraits (bloodwork not related to Lyme disease, symptoms, level of functioning), and who previously had erythema migrans.

**Pillar 1**

**Diagnostics**

# Pillar One group objectives

Pillar 1
Diagnostics

- Create a study protocol and attendant documents suitable for submission to Queen's HSREB by January 31, 2022 (Amended to April 30, 2022).

Before writing a full protocol, we need a single overall study objective.

# Challenges

Pillar 1
Diagnostics

- Our study must be contextualized within the 4 ClyDRN Pillars.
- We only have two Pillar One Scientists who can lead any proposed study.
- Constraints:  they can only perform work that can be conducted within the framework of a publicly funded provincial diagnostic laboratory.
- Our study needs to be applied rather than basic research.
- The samples they have on hand are positive serum samples (approx. 100-150 in each province).
- We do not have immediate access to biobank samples (Pillar 3).
- The overall study budget is about 200k.

# So far:

**Pillar 1**
**Diagnostics**

- Met with and discussed overall goals and objectives with all members of the Pillar One team.
- An early objective to measure the diagnostic accuracy of standard two-tiered testing with that of modified two-tiered testing in low endemic areas did not meet the expectations of the patient working group (PWG).
- Although not an outright rejection the PWG would like to see additional testing applied.
- We are having minuted weekly meetings as we work our way towards an agreed upon group of objectives for the current study.
- *We are also recontextualizing our objectives within the broader overlapping goals of the Network.*

# Progress to date

**Pillar 1**
**Diagnostics**

- Both Drs. Morshed and Patel are willing to go beyond the scope of the original objective and include selected extra testing to the samples they hold in their respective freezers.
    - Provided they are commercially available
- Pillar 1 scientists are also very open to collaborating with other ClyDRN scientists.

# Progress to date

Pillar 1
Diagnostics

- We are in the process of determining:
  - Exact number of samples available
  - Expected volume of leftover serum (range).
  - We have a short list of tests that are commercially available and are obtaining the price per test for:
    - EUROIMMUN IgG + IgM
    - Immunoblot recom Line Borrelia IgG by MIKROGEN
    - CXCL13
    - Zeus WCL/IFA
    - MarDx
- We will be able to retest available sera for the presence of infection not picked up with routine two-tier test protocols.
- Results may inform next steps for future studies that will require funding.

# PWG Perspective

- Everyone is very committed to the success of Pillar 1 and CLyDRN
- We are working very hard to explore
  - What ought to be done?
    - What diagnostic practices best meet the needs of the LD community?
    - What diagnostic investigation inputs and outputs will have the best impact on LD healthcare policy and practice?
    - Sensitivity, Specificity, LD Stage, Clinical presentation, Symptom profile, Outcomes
  - What is not possible to be done?
    - What are the P1 time and resource constraints on the ideal scope?
  - What is possible to be done?
    - Can we exploit some capacity in the resource and time through integration of CLyDRN or external resources, and enhance the scope?
  - What can be done?
    - What small question can we address and how does it fit into the larger investigative picture with future funding?