**OPTIMA**

Optimizing Patient Centered-Care: A Pragmatic Randomized Control Trial Comparing Models of Care In the Management of Prescription Opioid Misuse

**WHAT IS CRISM?**
The Canadian Research Initiative in Substance Misuse (CRISM) is Canada’s only dedicated research network for substance use interventions in building national and regional infrastructure for clinical, health services, and population health research in substance use and addictions.

**OPTIMA TEAM**

### Steering Committee

- **CRISM Nominated Principal Investigators (NPIs)**: Dr. Julie Bruneau, Dr. Benedikt Fischer, Dr. Cameron Wild, and Dr. Evan Wood, will act as the Steering Committee that will be consulted as needed to provide oversight and high-level direction from a research perspective. Dr. Bruneau, NPI for the CM Node, has been designated as the Chair of the Steering Committee. The Lead Regional Principal (Lead RPI) Investigator will also join this committee.

#### Regional Principal Investigators

- **British Columbia Node**: Eugenia Socias, MD & Keith Ahamad, MD
- **Ontario Node**: Bernard Le Foll, MD, PhD
- **Quebec-Montrealie Province**: Didier Jutras-Aswad, MD, MSc (Lead RPI)

Dr. Didier Jutras-Aswad has been designated by the Steering Committee as the Lead RPI, responsible for overall trial implementation and for providing oversight at a national level, as well as for initiating and ensuring regular communication with RPIs.

### National Research Coordinator

- **Bill Fikowski, MPH**

### Medical Monitors

- **British Columbia Node**: Scott MacDonald, MD
- **Ontario Node**: Bernard Le Foll, MD, PhD
- **Quebec-Montrealie Province**: Didier Jutras-Aswad, MD, MSc (Lead RPI)

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#### Regional Study Coordinators

- **British Columbia Node**: Katrina Blommaert, MPH
- **Ontario Node**: Bernard Le Foll, MD, PhD
- **Prairie Node**: Avisnder Aulakh, MD

**Regional Study Coordinators**

- **Ontario Node**: Bernard Le Foll, MD, PhD
- **Quebec-Montrealie Province**: Didier Jutras-Aswad, MD, MSc (Lead RPI)

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### Ancillary Study Investigators

- **Dr. Lindsey Richardson (Principal Investigator)**
- **Dr. Elaine Hyshka (Co-Investigator)**
- **Dr. Carla McLean (Co-Investigator)**

### OUTCOME MEASURES:

- **Primary outcome measure**
  - Opioid use
  - Secondary outcome measure
  - Retention

### OBJECTIVES:

- **Objectives**

### ADDRESSING RESEARCH GAPS:

- **Research gaps**
  - Randomized controlled trials evaluating opioid agonist treatments are done almost exclusively among heroin users.
  - There is a lack of study comparing buprenorphine/naloxone vs. methadone in real-world setting according to each drug safety profile.
  - Long-term opioid agonist treatment (e.g., > 6 months) is accessed by fewer than 10% of individuals with opioid use disorder.

### PRIMARY HYPOTHESIS:

- Buprenorphine/naloxone flexible take home dosing is non-inferior to methadone standard model of care in treating prescription opioid use disorder, as measured by the mean percentage of opioid-free urine drug screens during 24 consecutive weeks.

### STUDY DESIGN:

Participants will be randomized to receive either:

- a) Methadone provided via initial daily witnessed ingestion as per local guidelines
- b) Buprenorphine/naloxone maintenance therapy provided via flexible take-home dose regimens dispensed as per physician’s discretion, once clinical stability is achieved.

**STUDY END POINTS**

**Patient retention** will be determined for the 24-week intervention period and up to 4 weeks for randomization.

**Research visits** take place every 2 weeks (including collection of urine samples) for the 24-week intervention period.

**Clinic visits** take place at physician discretion or as needed by the participant.

**DURATION**

- **Up to 28 weeks**, including a 24-week intervention period and up to 4 weeks for randomization.

**Primary outcome measure**

- **Adherence**
- **Safety**
- **Treatment satisfaction**
- **Patient engagement**