CTN-0116: Implementing a Pharmacist-Integrated Collaborative Model of Medication Treatment for Opioid Use Disorder (PharmICO)

INFORMATION FOR POTENTIAL SITES

AUGUST 26, 2021

CTN-0116

PHARMICO

IMPLEMENTING A PHARMACIST-INTEGRATED COLLABORATIVE MODEL OF MOUD

NATIONAL DRUG ABUSE TREATMENT CLINICAL TRIALS NETWORK

CTN-NE

The National Drug Abuse Treatment Clinical Trials Network - Northeast Node

Meet the PharmICO Team Leads

Lead Investigator

Lisa A. Marsch, PhD

Co-Lead Investigator

Felicity Homsted, PharmD, MBA

Co-Lead Investigator

David Fiellin, MD

Meet the PharmICO Team Leads

Project Director

Bethany McLeman, BA

Project Co-Director

Phoebe Gauthier, MS, MPH

Meet the PharmICO Team

Udi Ghitza, PhD (Scientific Officer)
Center for the Clinical Trials Network, NIDA

Vernon 'Trip' Gardner, MD (Co-Investigator)
Psychiatrist, Penobscot Community Health Care (PCHC)

Lisa Saldana, PhD (Co-Investigator)
Implementation Scientist, Oregon Social Learning Center

Sarah K. Moore, PhD (Co-Investigator)
Qualitative Scientist, Dartmouth College

Paul Joudrey, MD (Co-Investigator)
Implementation Scientist, NIDA K awardee, Yale University

Jerry Cochran, PhD (Co-Investigator)
Pharmacy Scientist, University of Utah

Meet the PharmICO Team

Laurie S. Lester, PhD (Project Manager)
Northeast Node, Dartmouth College

Tess Gallant, BS (Research Assistant)
Northeast Node, Dartmouth College

Jesse Boggis (PhD Candidate)
Northeast Node, Dartmouth College

Abigail Matthews, PhD (Biostatistician)
DSC*, The Emmes Company

Edward Chongsi, PhD (Biostatistician)
DSC, The Emmes Company

Kathryn Hefner, PhD (DSC Project Leader)
DSC, The Emmes Company

Rebecca Ottesen, MS (Biostats Manager)
DSC, The Emmes Company

Jacklyn Harris, MA (Clinical Study Manager)
CCC**, The Emmes Company

*Data and Statistics Center

**Clinical Coordinating Center

CTN-NE
The National Drug Abuse Treatment Clinical Trials Network - Northeast Node

Meet the PharmICO Team

Noah Nesin, MD (Expert Consultant)
Chief Medical Officer, PCHC

Vijay Amarendran, MD (Expert Consultant)
Director of Addiction Services, PCHC

Frank McGrady, PharmD (Expert Consultant)
Director of Pharmacy, PCHC

Kris Ravin, PharmD (Expert Consultant)
Pharmacy Operations Manager, PCHC

Robert Zavaleta (Expert Consultant)
Information Systems Director of Operations and Data Analytics, PCHC

Dustin Corey (Expert Consultant)
Information Systems Data Analyst, PCHC

Various Patients (Expert Consultants)
Seaport Community Health Center, PCHC

Agenda

Item	Speaker
Purpose	Dr. Lisa Marsch
The PrIMO model	Dr. Felicity Homsted
Study Components	Dr. David Fiellin
Site Expectations	Bethany McLeman
Site Selection Process	Phoebe Gauthier

Purpose

DR. LISA MARSCH

Background and Significance

Pharmacists remain an underutilized resource in the treatment of opioid use disorder (OUD) in the U.S.

When pharmacists engage in patient care to their full capacity: physician time may be saved, access to care is expanded, clinical outcomes may be improved, and payers may view the economic implications more favorably.

Pharmacists may be available to participate in new roles that support providers given an anticipated 35% expansion in the workforce by 2025.

This study will evaluate the implementation of a standard care model of **P**harmacist-**I**ntegrated **M**edication treatment for **O**UD (PrIMO) from Penobscot Community Health Care (PCHC), a federally qualified health center in Maine.

Study Aims

Primary Aim

To evaluate the feasibility of implementing PrIMO into the workflow across 4 diverse clinical sites.

Secondary Aims

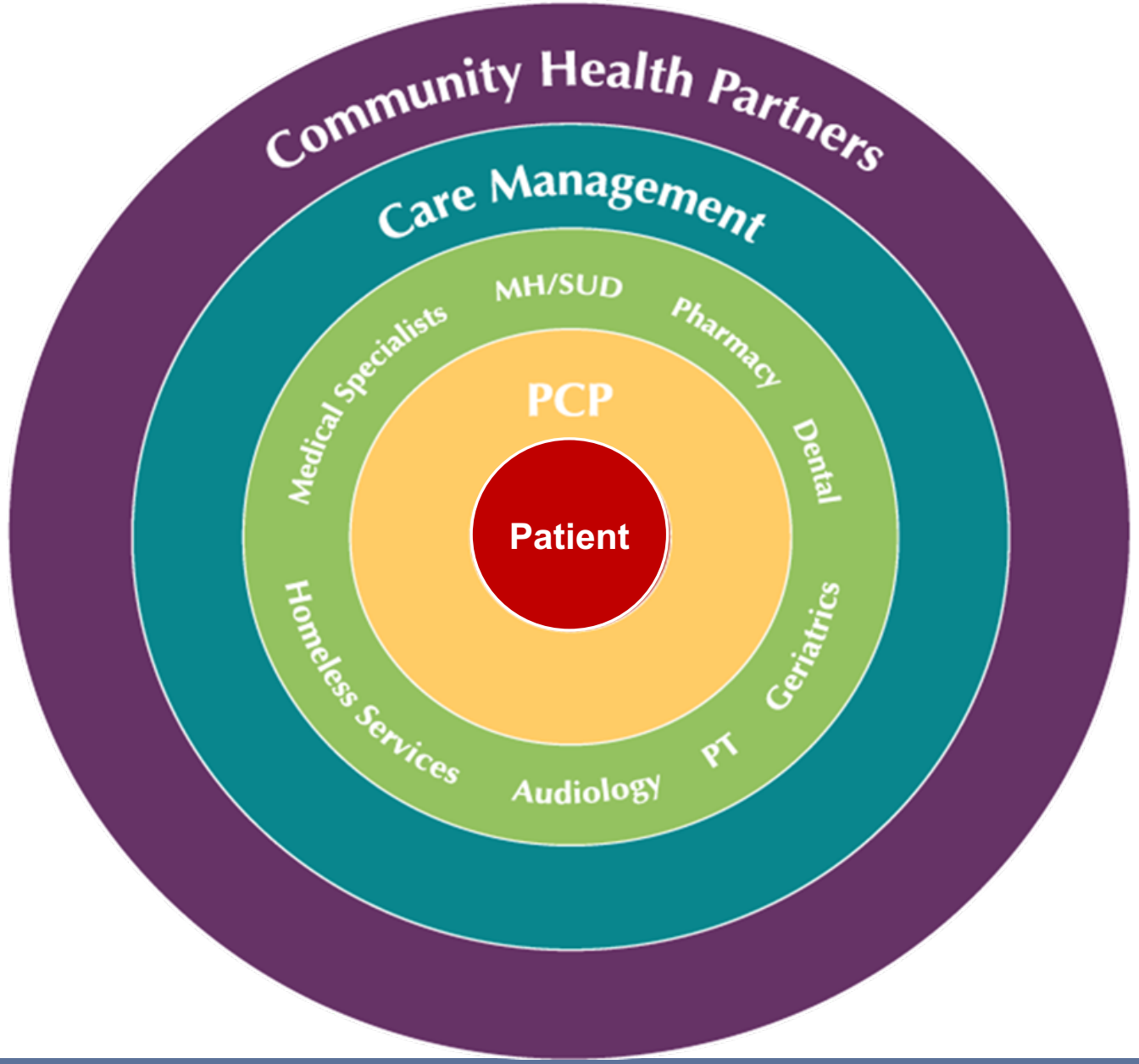
To evaluate the acceptability and impact of implementing the PrIMO model.

The PrIMO Model

DR. FELICITY HOMSTED

Brief Overview

- Developed by an interdisciplinary team at PCHC, led by Dr. Felicity Homsted and Dr. Trip Gardner in 2017.
- An integrated primary care clinical team (PCPs, pharmacy staff, psychiatrists, nurse practitioners, and behavioral health clinicians) works collaboratively in offering a full continuum of healthcare to persons with OUD.
- Pharmacist's role goes beyond filling medication orders; pharmacists will meet with the clinical team and patients to provide individualized care and education related to medication.
- This exemplary patient-centered model of care had been in place at PCHC for the management of complex medical conditions for years prior to its use in treating OUD.


Community Health Partners
Care Management
MH/SUD
Pharmacy
Dental
Geriatrics
PT
Audiology
Homeless Services
Medical Specialists
PCP
Patient

History of the PrIMO Model

Developed as a response to community needs at Hope House, serving a large homeless population; unique circumstances brought the pharmacist to the table.

PCHC clinical staff and leadership soon realized how vital the pharmacist could be in the care team for all MOUD treatment.

Soon after the launch of PrIMO, the number of MOUD prescribers increased from **4 to 24** and **positively increased staff's attitudes** toward addiction across the FQHC.

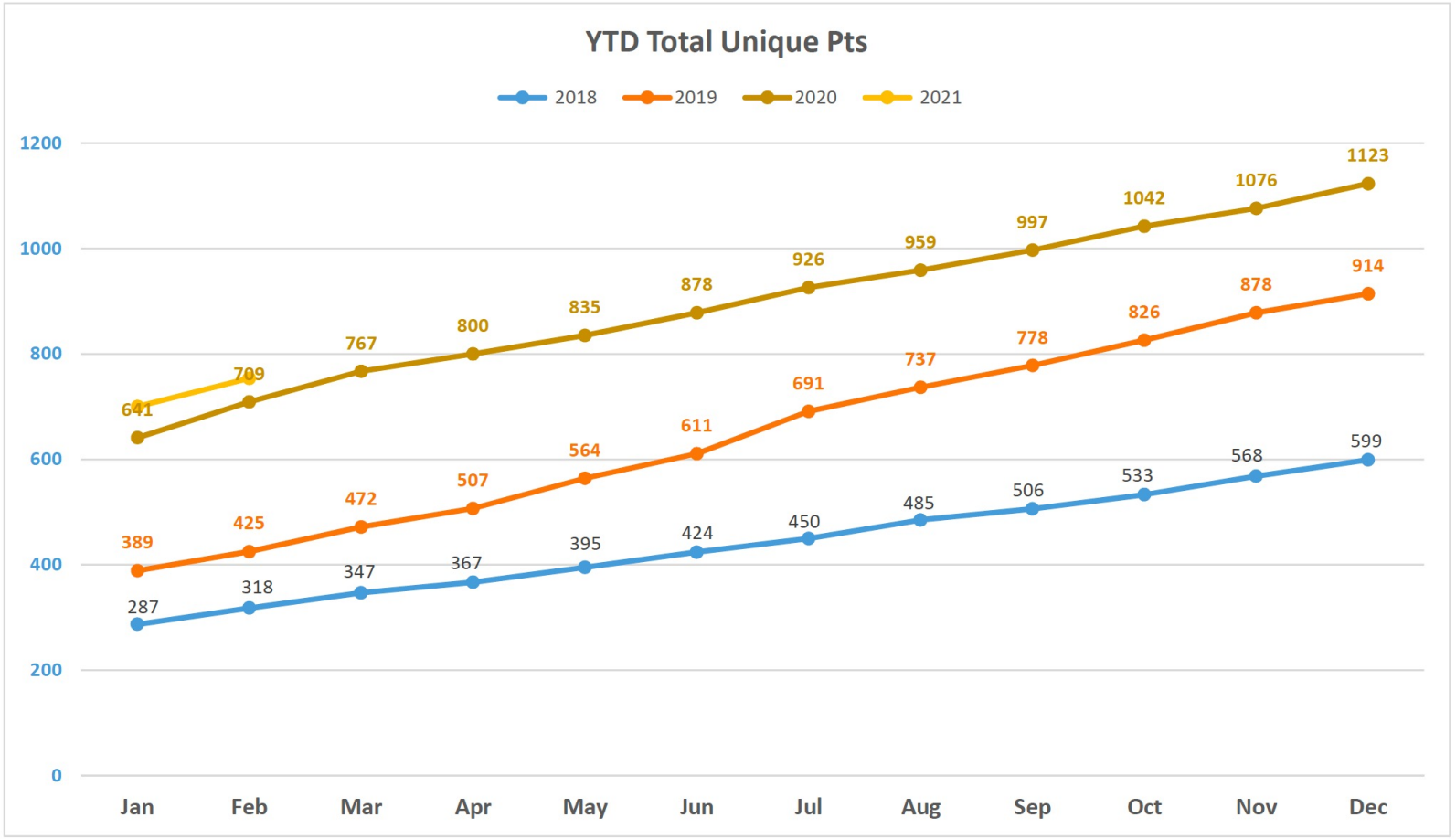
History of the PrIMO Model

PCPs reported that PrIMO helped **alleviate concerns** about delivering medication treatment for OUD.

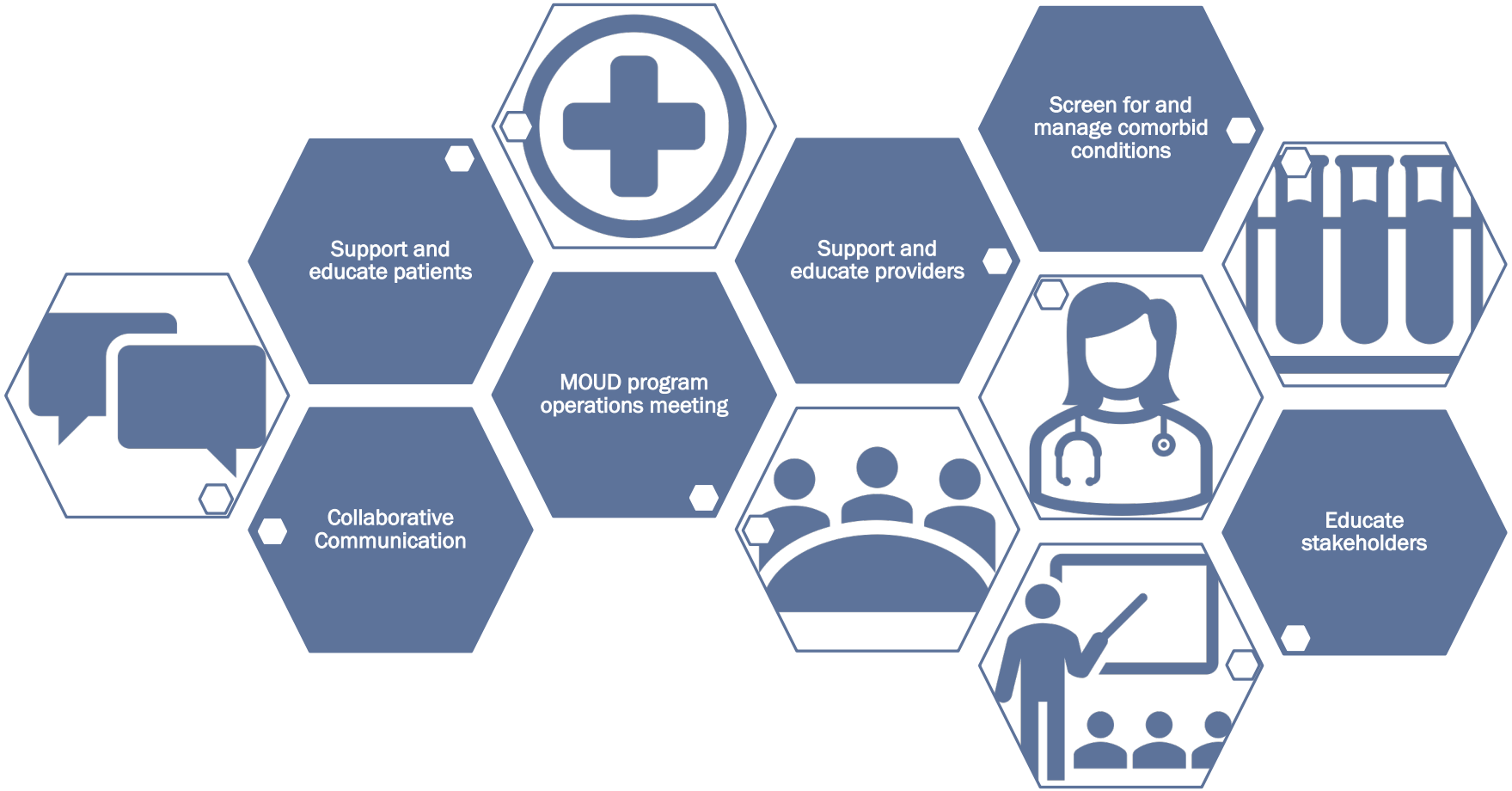
PCPs reported that it **allowed them to prescribe** medication for OUD instead of referring patients to addiction specialty settings.

Within 1 year of launch, this model was implemented in **two additional** PCHC health center pharmacies.

Number of patients in buprenorphine treatment across PCHC sites over time



PrIMO Core Components



PrIMO Team Members

PRIMO TEAM MEMBERS	DESCRIPTION
Core Team Members	Pharmacist At least one prescriber Behavioral health specialist
Ancillary Team Members	Case manager/social worker Medical assistants Program or office manager
Occasional Support members	As needed, depending on clinic and community needs Examples include dentists, cardiologists, vocational therapists, residents, etc.

Study Components

DR. DAVID FIELLIN

Five Study Elements

Implementation measures

Implementation Facilitation (IF)

Participant assessments

PrIMO fidelity measure

EHR data extraction

Element 1: Implementation Measures

Implementation measures

Element 1: Implementation Measures

Collected at the Site level

Sites will enter dates of milestone completion into a web-based instrument called the Stages of Implementation Completion (SIC)

- The SIC will capture clinics' progress across 8 stages of implementation
- Will provide real-time feedback to the clinic and Lead Team
- Sister instrument, the Cost Of Implementing New Strategies (COINS), will help to measure the cost of implementing PrIMO

Element 2:
Implementation Facilitation (IF)

Implementation
Facilitation (IF)

Element 2: Implementation Facilitation

Support the sites in implementing PrIMO.

Use a variety of strategies to identify needs and address barriers as they arise.

Formative evaluation	Provider education & academic detailing
Advising on clinical intervention	Program marketing
Stakeholder engagement	Performance monitoring & feedback
Tailor program to site	Learning collaborative with continuing education credits

Element 3:
Participant Assessments

Participant assessments

Element 3:
Staff Participant Assessments

Research staff will conduct survey assessments with site staff participants.

Stakeholder	Min–Max per site
Providers	5-20
Pharmacists	2-6
Pharmacy technicians	2-10
Administrators	2-10

Survey assessments will include measures of:

- Perceptions of implementation (including barriers and facilitators, acceptability, appropriateness, etc.)
- Perceptions of sustainability
- Biases in treating OUD
- Perceived barriers and beliefs of MOUD
- Support of implementation

*The Lead Team will also conduct qualitative interviews with a subset of the stakeholder groups at designated timepoints.

Element 3: Participant Assessments – Patients

Research staff will conduct research assessments with patient participants.

Patient baseline will occur after at least 2 weeks of exposure to the model.

	Min–Max per site
Patients	12-40

Assessments will include measures of:

- Perceptions of implementation (including barriers and facilitators, acceptability, appropriateness, etc.)
- Experience of stigma toward MOUD

*The Lead Team will conduct qualitative interviews with a subset of the stakeholder groups at the designated timepoints.

Element 4:
PrIMO Fidelity Measure

PrIMO fidelity measure

Element 4:
PrIMO Fidelity Measure

PrIMO Model Checklist

Weekly review of the site's fidelity to the PrIMO model

Web-based data entry by a member of the PrIMO team at the end of each weekly operations meeting

Feedback will also be used to guide implementation support

Element 5:
EHR Data Extraction

EHR data extraction

Element 5:
EHR Data Extraction

IT Specialist to join data meetings at study start (prior to endorsement) to begin building Data Dictionary and data harmonization procedures.

The study will utilize a combination of electronic data from both the **clinic** and **pharmacy** EHR systems. Sites will be expected to link clinic and pharmacy data (e.g., de-identified crosswalk or combined dataset).

Data Collection will span 12 months pre-PrIMO launch and 12 months post-PrIMO launch.

Example:

-12 MONTHS	-9 MONTHS	-6 MONTHS	-3 MONTHS	LAUNCH	3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS
4/1/21	7/1/21	10/1/21	1/1/22	4/1/22	7/1/22	10/1/22	1/1/23	4/1/23

Site Expectations

BETHANY MCLEMAN, PROJECT DIRECTOR

Site Criteria

Participating sites must be primary care clinics serving adult patients and meet the following criteria to be selected:

- ✓ Have a clinic-based pharmacist and retail pharmacy (employed or owned by the clinic organization; co-located with the clinic is optimal).
- ✓ Have one pharmacist and one primary care provider to serve as champions for the study.
- ✓ Agree and be able to provide non-identifiable clinic and pharmacy EHR data to the study team.
- ✓ Have shared access for the pharmacist to the clinic's EHR system.
- ✓ Reflect a diverse patient population (e.g., gender, race, ethnicity, geography).
- ✓ Already be prescribing MOUD, including buprenorphine, with at least one active X-waivered provider.
- ✓ Agree to cede oversight to the study's single IRB, The Biomedical Research Alliance of New York (BRANY).

Commercial or private community pharmacies will not be included unless they already work very closely with the clinic and can have, or already have, EHR access.

Potential sites will be excluded if they already have a model of integrated MOUD with a pharmacist or are providing an adequate volume of MOUD to their community, to be determined by the Site Selection Executive Committee as part of the site selection process.

Site Expectations by Study Element

STUDY ELEMENT	DESCRIPTION	ANTICIPATED ROLE
Implementation measures	Enter dates of implementation milestones into a web-based dataset (the Stages of Implementation Completion measure)	Pharmacist Champion
Implementation Facilitation	Participate in at least weekly meetings (some team members will be expected to participate in additional meetings, to be determined with the Lead Team)	Pharmacist Champion Provider Champion
Participant Assessments	Work with their local CTN Node to assist in the recruitment of study participants (both site staff and patients)	Limited; potentially Champions or leadership
PrIMO fidelity measure	Complete a weekly survey related to the site's fidelity to the PrIMO model	Pharmacist Champion
EHR data extraction	Meet approximately weekly with the Lead Team to refine and implement EHR data extraction procedures (i.e., develop and manage a site-specific Data Dictionary) throughout the study period	IT specialist

Site Staffing Estimations

ROLE	DESCRIPTION	ANTICIPATED EFFORT
Pharmacist Champion	PharmD or RPh employed at the site, serving in the role of pharmacist.	20% FTE
Provider Champion	Waivered primary care provider employed at the site.	10% FTE
Information Technology (IT) Specialist	Team member familiar with the clinic and pharmacy EHR systems.	40% FTE
Site Principal Investigator (PI)	Clinic team member (MD, PhD, or equivalent experience) employed at the site with the ability to provide oversight and leadership to the project.	5% FTE

Additional research staffing will be provided, either to the local Node or to the site, depending on structure.

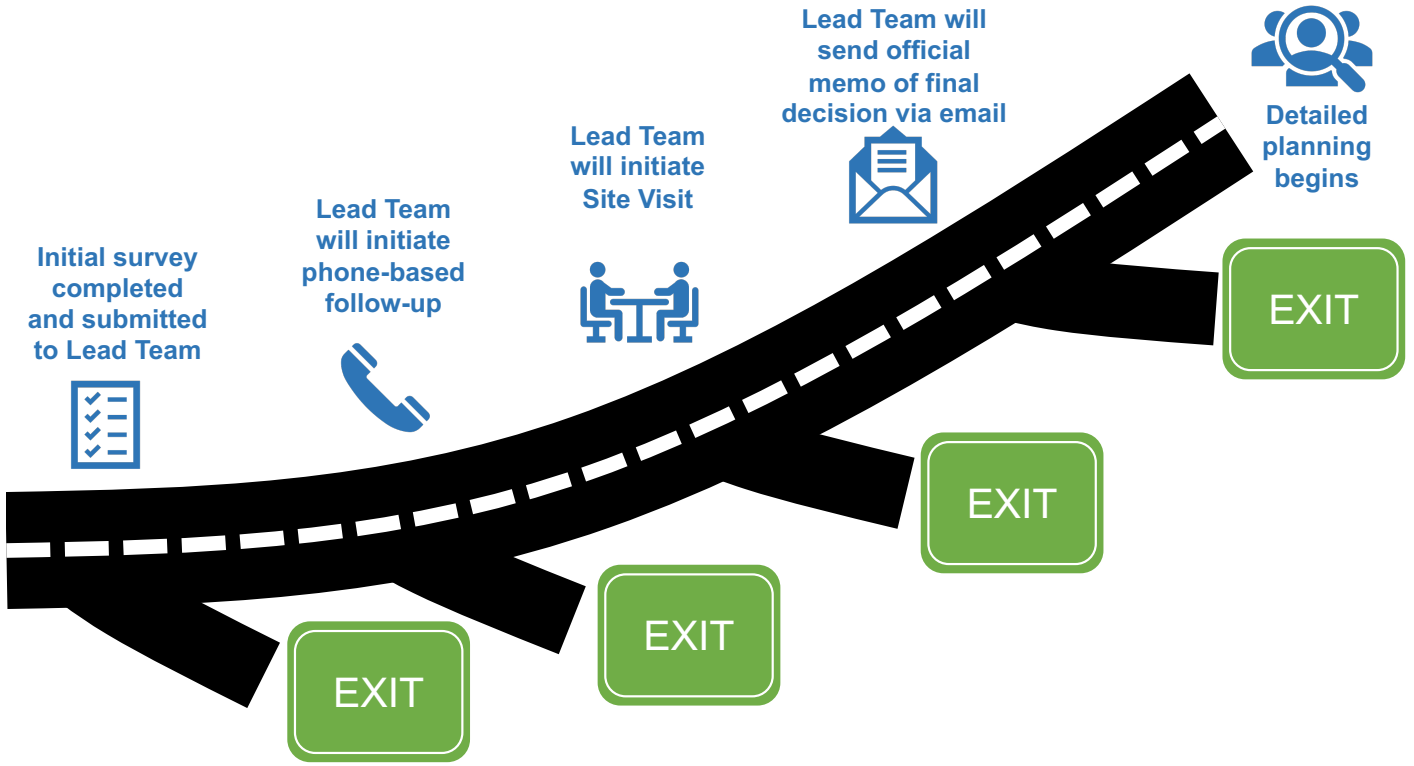
What the Lead Team is Seeking

- Sites interested in changing the way they treat OUD and willing to invest in this model
  - Be willing to allow various clinic and pharmacy staff have dedicated meeting times once per week
- Dedicated team members
  - Champions and IT Support
- Join our TEAM!
  - We have a great team and are looking for partners to join us in our scientific discovery!

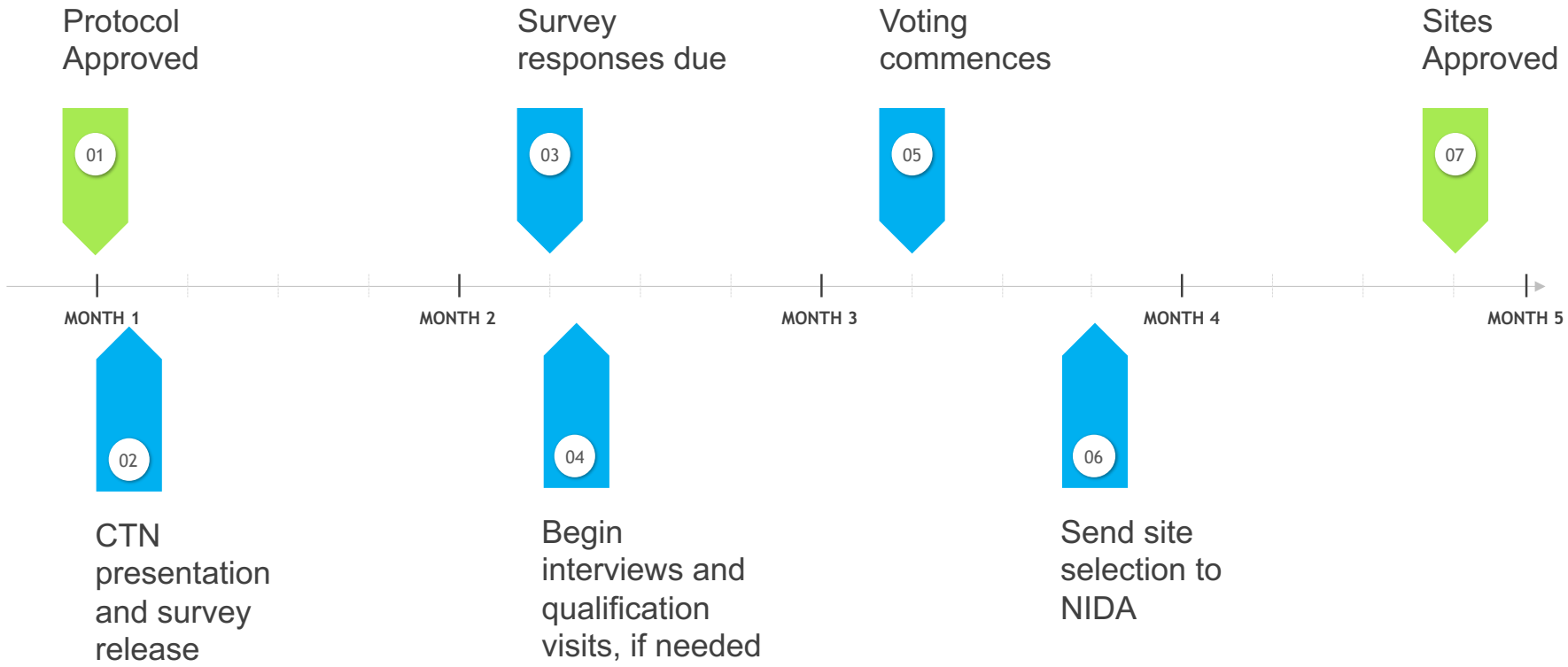
Site Selection Process

PHOEBE GAUTHIER, PROJECT CO-DIRECTOR

CTN Site Selection Process



CTN-0116 Lead Team Considerations



Voting on Key Constructs

1. Material completion
2. Integration and Communication
3. Perceived commitment and support
4. Diversity
5. Recruitment potential
6. EHR Capabilities

Site Selection Survey

Sent to local nodes on Monday, August 23

Completed surveys due back to the Lead Team by Friday, October 1

Email completed surveys to: Northeast.Node.CTN@Dartmouth.edu

*There is a component to the survey for which sites will need to pull some EHR data from the clinic and pharmacy systems.

- The reports may be used during the interview phase to send a “test file” to ensure that EHR data transfers can occur. The Lead Team recommends storing/saving these initial reports to use as this test file.


Questions and Answers

Extra slides

Outcomes by Aim

Aim	Outcome	Measure
Aim 1: Feasibility (primary outcome)	Feasibility of implementation at 4 study sites	Stages of Implementation Completion
Aim 2: Acceptability (secondary outcome)	Stakeholder perceptions of implementation (including barriers and facilitators, acceptability, appropriateness, etc.)	Applied Mental Health Research D&I Tool; Qualitative Interviews*
	Stakeholder perceptions of sustainability	Clinical Sustainability Assessment Tool; Qualitative Interviews*
	Biases of treating OUD	Medical Conditions Regard Scale; Qualitative Interviews*
	Patient experienced stigma of MOUD	Substance Use Stigma Mechanism Scale; Qualitative Interviews*
	Provider perceived barriers and beliefs of MOUD	Beliefs on MOUD Survey; Qualitative Interviews*
	Site staff support of implementation	Implementation Citizenship Behavior Scale; Qualitative Interviews*
	Site fidelity to the PrIMO model	PrIMO Model Checklist
	Cost of implementation	Cost of Implementing New Strategies
Aim 2: Impact (secondary outcome)	Site patient outcomes	EHR data extraction
	Site capacity for MOUD	EHR data extraction

*A single qualitative interview may gather data that span multiple constructs.

Participant Incentives

Stakeholder group	Assessment period	Quantitative incentive	Qualitative* incentive
Site Staff	Pre-PrIMO Launch	$100	$100
	At Launch	$100	$100
	3 months post-Launch	$100	$100
	6 months post-Launch	$100	$100
	9 months post-Launch	$100	$100
	12 months post-Launch	$100	$100
	Potential total	*$600*	*Up to $1,200**
Patients	Baseline	$100	$100
	3 months post-baseline	$100	$100
	6 months post-baseline	$100	$100
	Potential total	*$300*	*Up to $600**

**A portion of those who complete quantitative assessments will be invited to participate in interviews*