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

EHR DATA EXTRACTION SUMMARY

BRIEF PROJECT SUMMARY

This project will implement a pharmacist-integrated model of medication treatment for opioid use disorder (called the PrIMO model) at four diverse sites across the US and will evaluate the feasibility, acceptability, and impact of implementing this model of care.

DESCRIPTION/PURPOSE OF EHR DATA EXTRACTION

To assess the impact on clinical sites' capacity for medication treatment for opioid use disorder (MOUD) and on patient outcomes during MOUD over time, the study will use EHR data fields described below to determine aggregate site-level changes from 1 year prior to launch of the PrIMO model and 1 year post launch.

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).

It is vital that sites provide harmonized data from both systems linked by a de-identified patient ID at regular intervals throughout the project, as specified by the EHR study data dictionary and upload specifications plan.

DATE RANGES

Visit Date Range: 12 months prior to PrIMO launch – 12 months after PrIMO launch
For example, if PrIMO launch occurs on 4/1/2022 date ranges would be:

-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

Birthdate Age: 18+ at time of appointment

MEDICATIONS INCLUDED

EHR data related to MOUD refers to any of the following medications and all associated formulations (including long acting)**:**

- Buprenorphine
- Buprenorphine/naloxone
- Naltrexone

SAMPLE OUTCOMES FROM THE CLINIC AND PHARMACY EHR

DESCRIPTION	SUBSET	GOAL	EXCLUSIONS	POTENTIAL DATA ELEMENTS
Patients prescribed MOUD: Patients diagnosed with opioid use disorder who have been prescribed MOUD (buprenorphine, naltrexone) at least 1 time within the past 90 days	Total unique patients seen by the clinic	Total patients prescribed MOUD	All patients under the age of 18	Site ID Patient ID OUD Diagnosis (ICD) Patient Age (years) Visit date (mmddyyyy) MOUD drug name Date MOUD order placed (mmddyyyy)
Providers capacity for MOUD: Providers prescribing MOUD (buprenorphine, naltrexone) at least 1 time in the past 90 days	All providers with DEA licenses to prescribe controlled substances	Total prescribers ordering MOUD at least 1 time	Providers not able to prescribe controlled substances	Site ID Provider ID Provider License # MOUD drug name Date MOUD order placed (mmddyyyy)
Patients per provider: MOUD patients treated per prescriber	Prescribers with DEA licenses to prescribe controlled substances	Unique patients prescribed MOUD	Providers not able to prescribe controlled substances; All patients under the age of 18	Site ID Patient ID Provider ID Provider License # Visit date (mmddyyyy) MOUD drug name Date MOUD order placed (mmddyyyy) Date MOUD filled/dispensed (mmddyyyy)
Patient retention in treatment: Documented fills of pharmacy orders for clinic patients of any MOUD.	Dates orders placed	Dates orders dispensed	Non-FDA approved use of medications for treatment of OUD; All patients under the age of 18	Site ID Patient ID MOUD drug name Date MOUD order placed (mmddyyyy) Date MOUD filled/dispensed (mmddyyyy)

PREPARING THE REPORT

Sites will work with the Lead Team to map existing EHR data to the PrIMO Data Dictionary for both the clinic and pharmacy EHR systems. This work will begin immediately following site selection, with the first extraction of EHR data anticipated for sharing with the Lead Team around the time the PrIMO model launches at the site and then transferring cumulative data approximately every 3-6 months thereafter, up to 18 months after the PrIMO model launch.

Sites will be expected to harmonize their data submission per the EHR data dictionary specifications, prior to sharing EHR data with the Lead Team, to be discussed throughout the Site Selection process and during study startup.

SHARING FILES

A Data Use Agreement (DUA) will be required to share these data with the Lead Team. The DUA will be executed between the clinic and pharmacy organization and the Data and Statistics Center (DSC), a component of The Emmes Company, LLC. The Emmes Company, LLC is a Contracted Research Organization (CRO) with the study sponsor, the National Institute on Drug Abuse (NIDA), and will manage and analyze these data alongside the study's lead investigators.