

Implementation of the American College of Physicians Guideline for LBP IMPACT-LBP

Data Overview

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

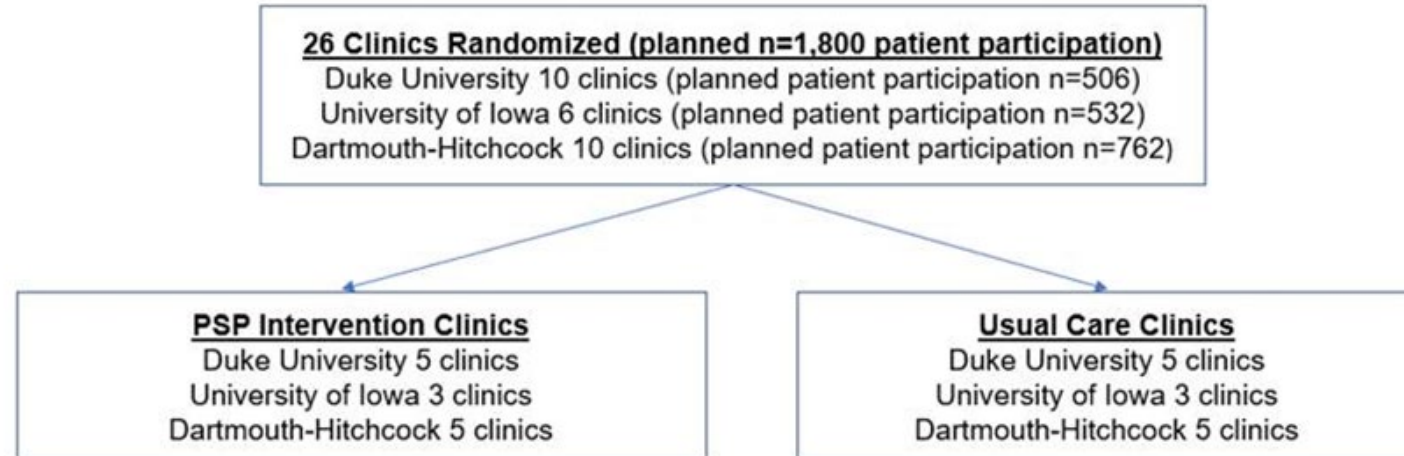
Rethinking Clinical Trials®

IMPACT-LBP Study Design

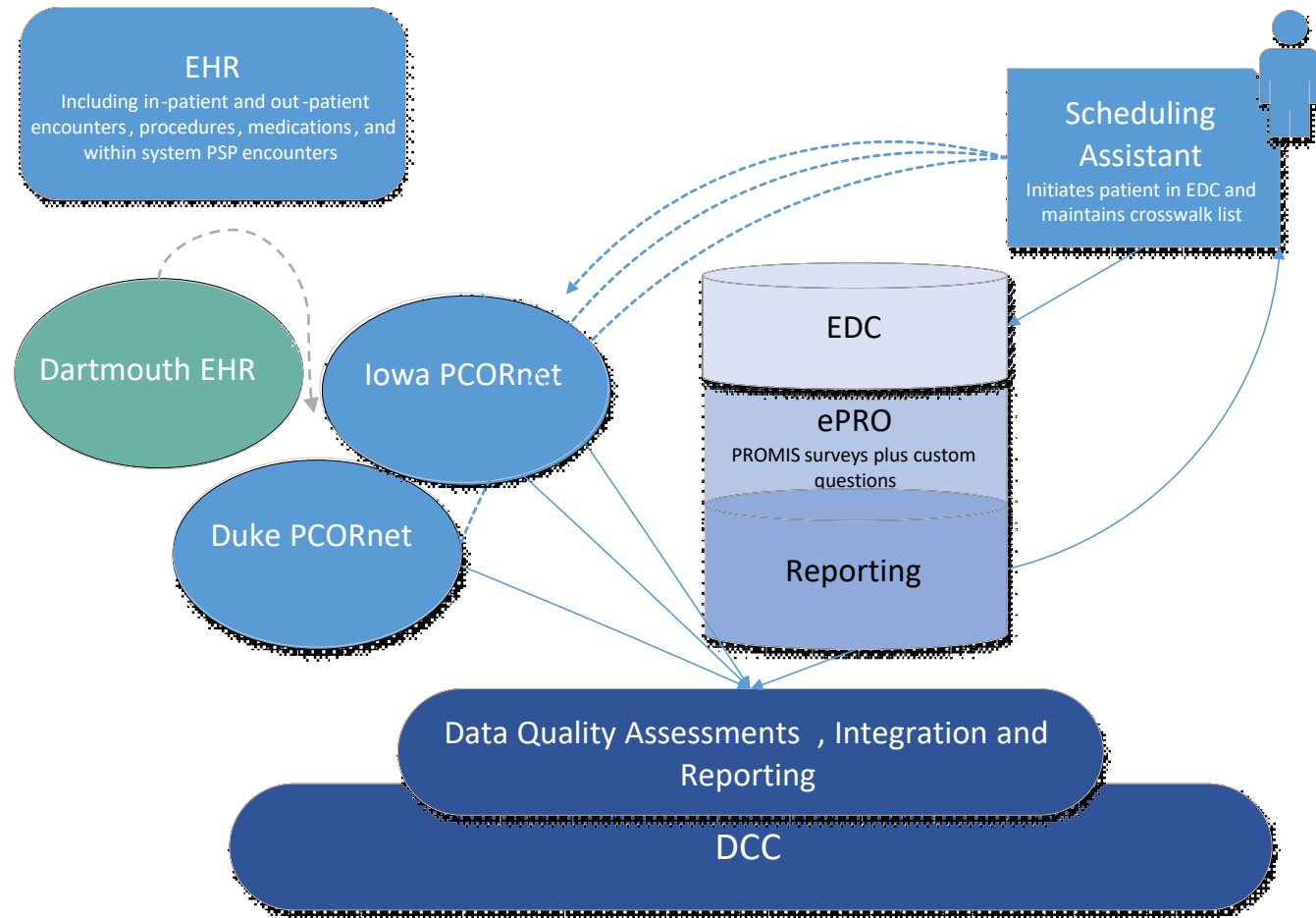
Study Design

- Pragmatic multi-site two-arm cluster-randomized trial with the unit of randomization at the primary care clinic level.
- 26 Family Medicine, Primary Care and General Internal Medicine Clinics.
- A total of 1,800 patients >18 years with a primary complaint of LBP who contact a participating primary care clinic to make an appointment with a primary care provider.

Intervention and Usual Care Clinics



IMPACt-LBP Data Flow



Common Data Models

- OMOP, PCORnet, etc.
- Ensures data harmonization across sites
- May include standard quality checks
- Increased collaboration and sharing knowledge / lessons learned

IMPACT-LBP EHR Data Challenges

- Two of the three sites provided EHR data in PCORnet format, with the existing network data curation checks in place. Data available per standard network timelines.
- One site providing raw EHR data
 - Not mapped to PCORnet
 - Not subject to the corresponding PCORnet data curation, including model population and consistency checks
- Impact:
 - Identify external group to map raw to PCORnet formats
 - Necessitate additional data checking by DCC
 - Impacted timelines and availability of data to DSMB
 - Impacted budget allocations
- Attempts to align data refreshes with DSMB Meetings
 - DSMB Schedule was not finalized; however PCORnet reloads quarterly