Towards a Scalable Informatics Platform for Enhancing Accrual into Clinical Research Studies

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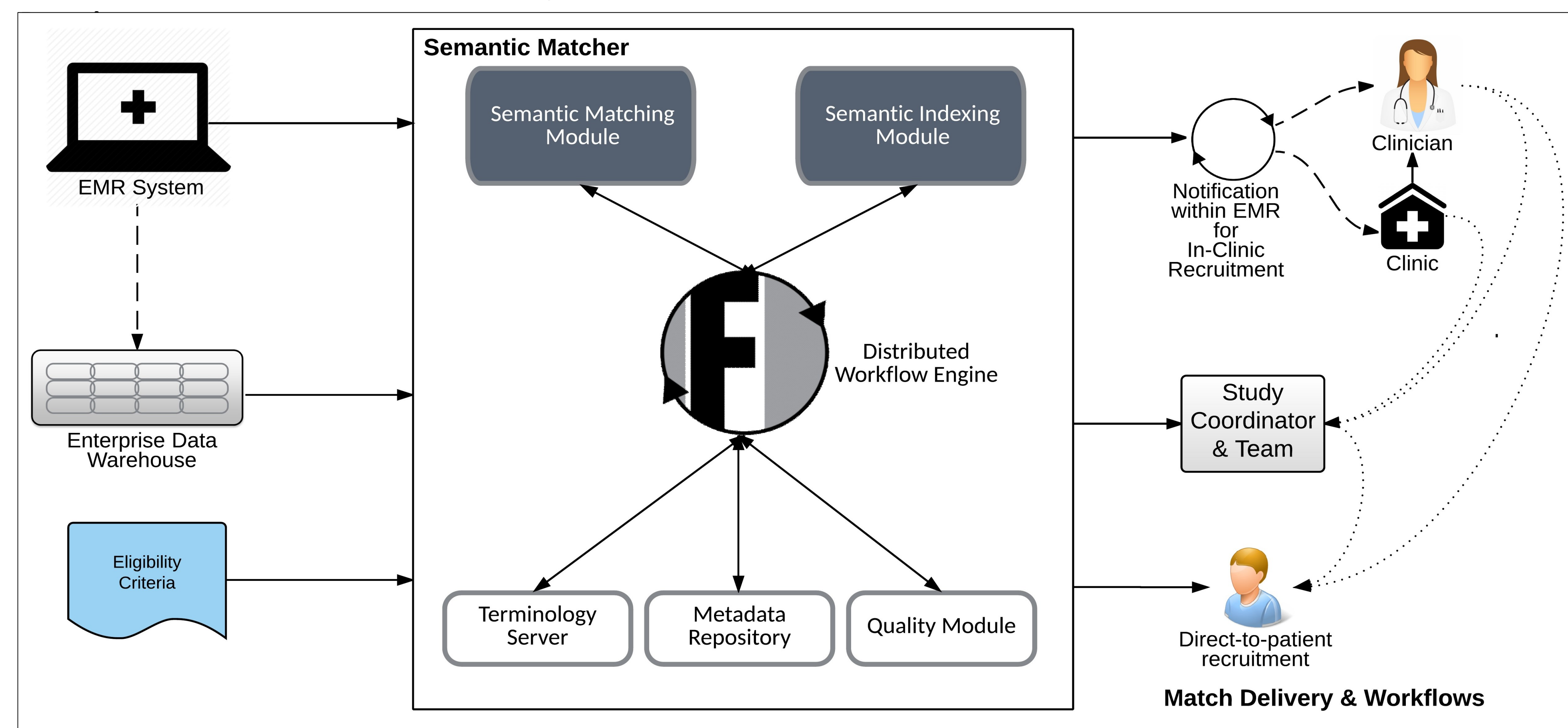
Introduction

- Issues with recruiting targeted number of participants in a timely manner often results in underpowered studies.
- More than 60% of clinical studies fail to complete or requiring extensions due to enrollment issues.
- Objective of this study is to develop and implement a scalable, organization wide platform to enhance accrual into clinical research studies.

Methods

- We are developing and evaluating an informatics platform: Utah Utility for Research Recruitment (U2R2) consisting of:
  - Semantic Matcher: An automated trial criterion to patient matching component that reports uncertainties associated with the match
  - Match Delivery: mechanisms to deliver lists of matched patients for different research and clinical settings
  - Structured Trial Criteria Capture.
- As a first step, we limited the Semantic Matcher to utilize only structured data elements from the patient record and trial criteria.
- We evaluated this first phase of U2R2 for an ongoing randomized trial with a target enrollment of 220 participants that compares two treatment strategies for managing back pain (physical therapy and usual care) for individuals consulting a non-surgical provider and symptomatic less than 90 days.
- Study team notified of matching patients on a biweekly basis.

Recruitment Processes within Utah Utility for Research

Match Delivery & Workflows

Example eligibility criteria and REDCap-based discrete capture form with embedded branching logic for metadata and modifiers
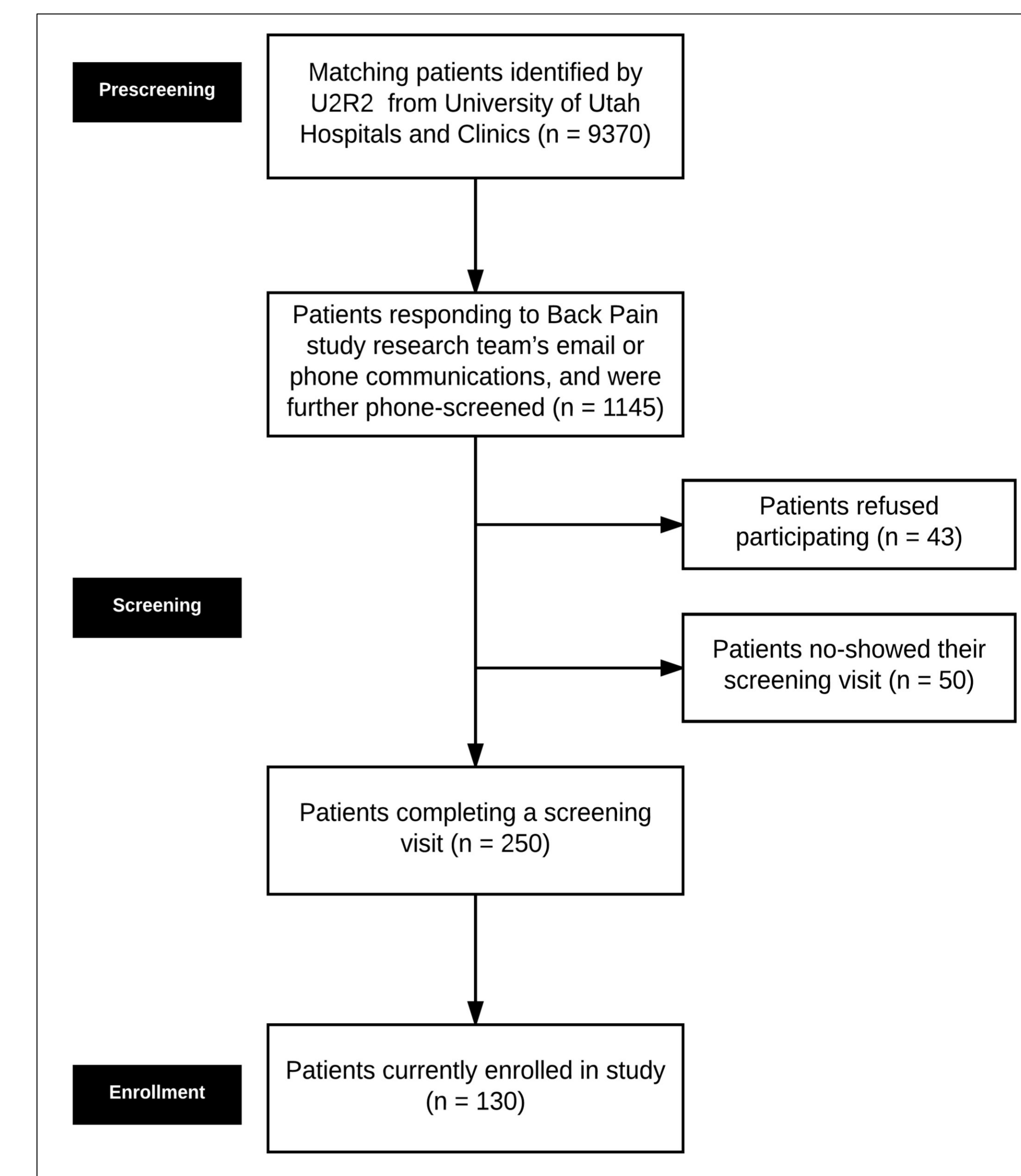
Current recruitment results for *Back Pain* study

Discussion

- Recruitment platforms can enhance potential participant identification.
- Development and operationalization of such platforms requires attention to multiple issues involved with clinical research studies.
- Unstructured data
  - Clinical eligibility criteria are usually unstructured and require human mediation and abstraction into discrete data elements for matching against patient records.
  - Key eligibility data are often embedded within text in the patient record.
  - Distributional semantic approaches, by leveraging this content, can identify potential participants for screening with more specificity. *(See poster titled "Semantic Characterization of Clinical Trial Descriptions from ClinicalTrials.gov and Patient Notes from MIMIC-III")*
  - Structured capture of eligibility criteria could improve match performance.
- Match Delivery: Workflows and thresholds for delivery of matched patients should consider characteristics of : (1) Research study, (2) Population, (3) Targeted enrollment, (4) Organizational and socio-technical issues surrounding clinical practice and research, (5) Standards for messaging (FHIR).
- Utilizing user-centered design approaches and including clinicians, clinics, and patients in recruitment workflows could yield higher accrual indices.

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