

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

Ramkiran Gouripeddi^{1,2}, Mollie Cummins^{1,2,3}, Elizabeth Lane⁴, Randy Madsen², Ryan Butcher², Jianyin Shao¹, Katherine Sward^{1,2,3}, Bernie LaSalle^{1,2}, Robinson Singleton^{2,5}, Julie Fritz³, Julio Facelli^{1,2}

¹Department of Biomedical Informatics, ²Center for Clinical and Translational Science, ³College of Nursing, ⁴College of Health, ⁵Department of Internal Medicine, University of Utah, Salt Lake City, Utah, USA

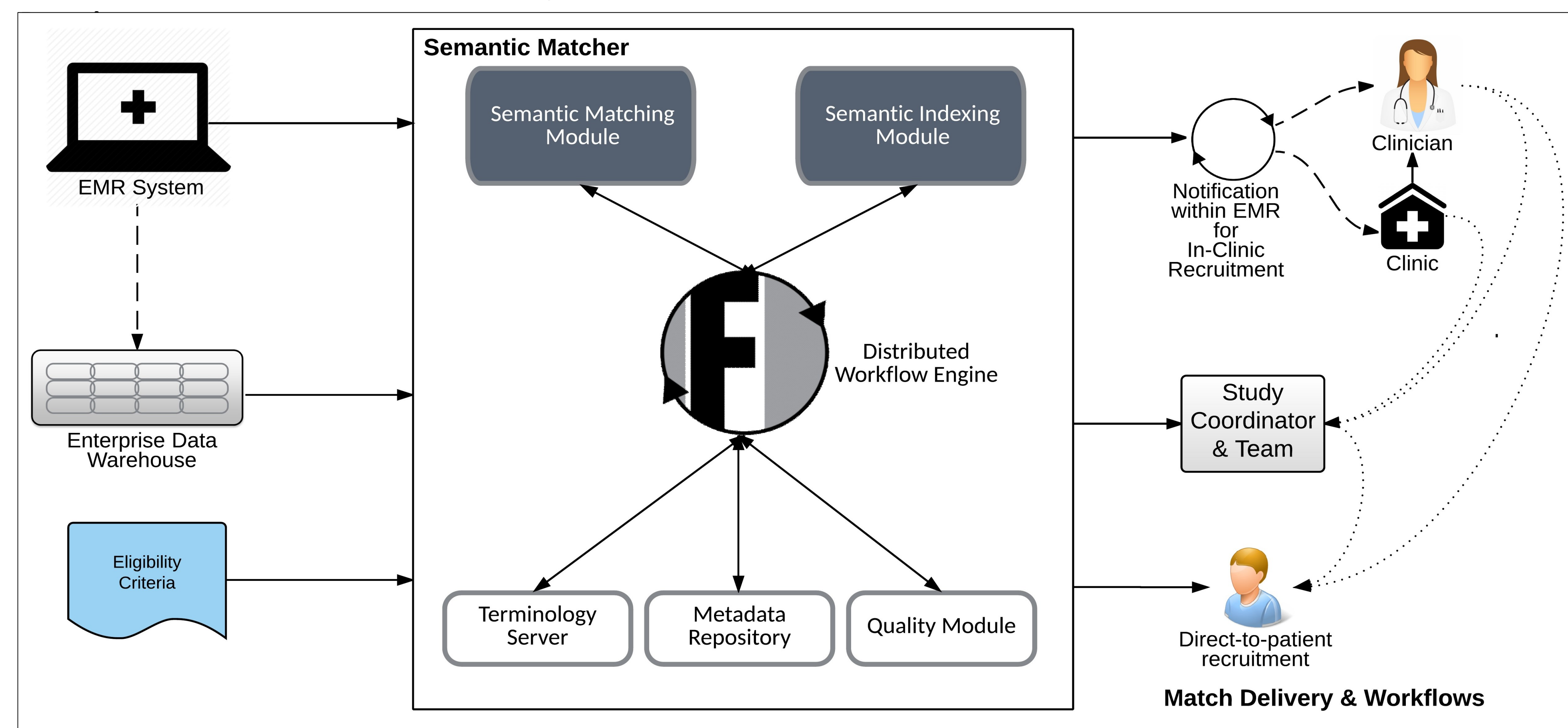
Introduction

- 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



Eligibility

Ages Eligible for Study: 18 Years to 80 Years (Adult, Senior)
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Intensive insulin treatment
- specific interest in "Diabetes and Partnership"
- wish to participate in group education
- informed consent
- fluent in reading and speaking German language

Exclusion Criteria:

- diabetes duration < 4 week
- severe organic disease (e.g. terminal renal disease, cancer with poor prognosis)
- current treatment of a mental disease
- cognitive impairment
- dementia
- pregnancy

Study ID:

Project Name:

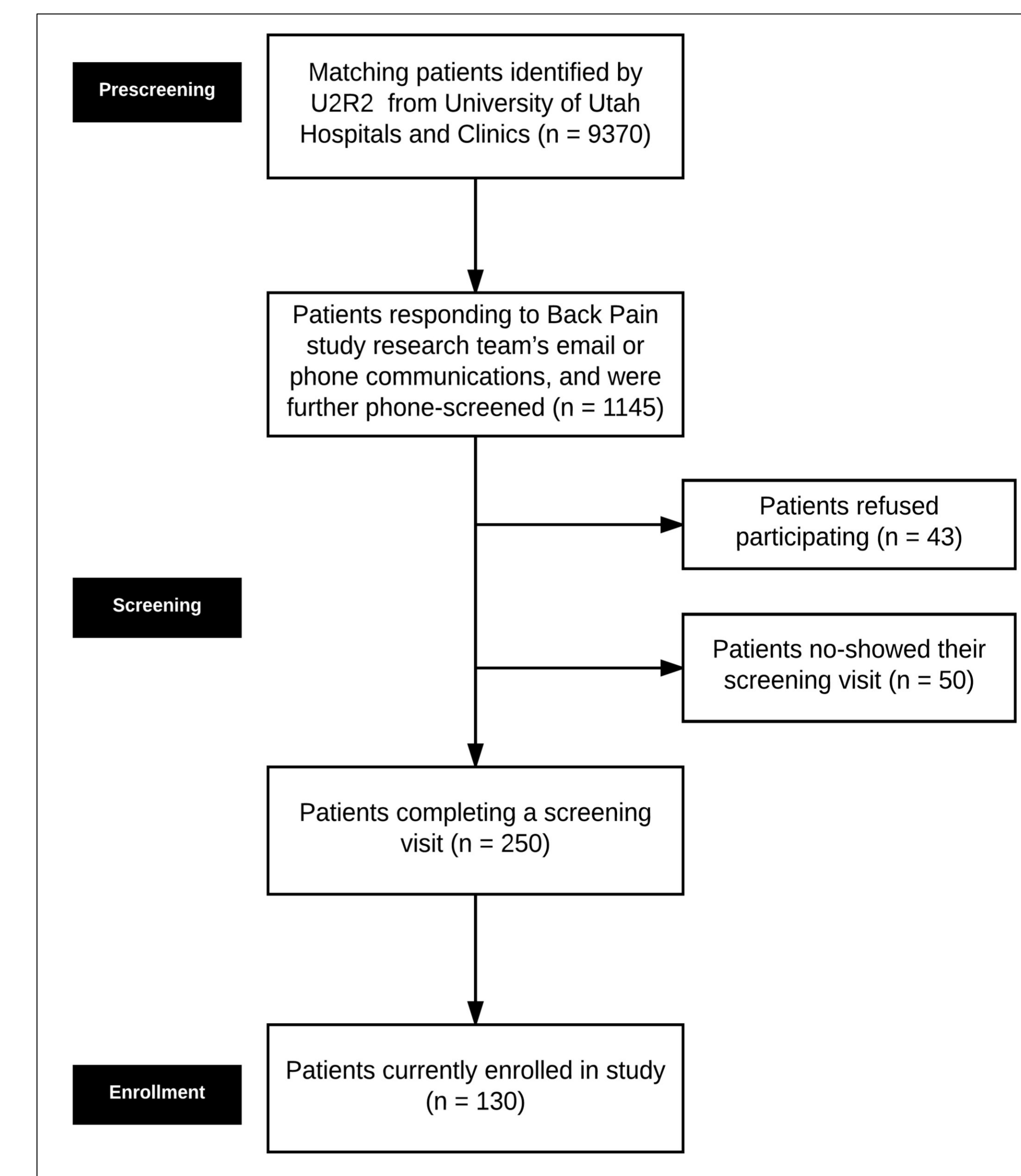
Eligibility Criteria 1: Condition Procedure Medication Laboratory Test

Eligibility Criteria 1 Temporal Modifier:

Eligibility Criteria 2: Condition Procedure Medication Laboratory Test

Eligibility Criteria 2 Temporal Modifier:

Example eligibility criteria and REDCap-based discrete capture form with embedded branching logic for metadata and modifiers



Current recruitment results for Back Pain study

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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.