Automated Clinical Trial Patient Matching System based on real-world data

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Patients who had visited to the YNHH GI Oncology department between 07/01/2020 to 12/31/2020 were included in the study to validate the accuracy and efficiency of the matching algorithms. Within the selected time period, 4,204 patients with 5,106 encounters (including different types of visits and EHR system generated encounters) were included. Patient’s visits were grouped by week, and only patient’s data prior to the corresponding visit was used for eligibility evaluation. Patient’s data was extracted from the OMOP CDM data repository and pre-processed for filtering in the next step. A short list of eligible patients was generated by filtering the information from the pre-processing step and was sent to the research team for validation and chart review. The baseline percentage of benchmarking was defined as gold-standard manual chart review of all the patients visiting the GI Oncology department within a designated week to identify the eligible patients for the trial. A machine-generated filtered patient list was compared to the gold-standard chart review performed by an experienced clinical trial manager. Result of alpha version patient matching system saw a several-fold increase in efficiency (total chart review workload decreased 10 times and average chart review time decrease 41%) and performance as follows: accuracy 94.4% (sensitivity), 100% precision (positive predictive value), 40% and specificity, 94.2%. Interviews with the clinical team indicated the tremendous potential impact of our system given use of ease and marked improvement in efficiency. Further analyses suggest the trial matching algorithms identifies eligible patients that include a significantly higher percentage of under-represented minorities than are currently enrolled in therapeutic trials nationally and at Yale. Summary We have successfully demonstrated that an automated, scalable, real-time and HIPAA/21 CFR-compliant pipeline can pre-screen eligible candidates for clinical trials. Few studies have developed an automated patient matching pipeline that can ingest and process data automatically in a real-time setting based on common data model. Our system greatly increased efficiency and decreased the workload of chart review. The accuracy of the system-identified patient list was comparable to human chart review, and none of the eligible patients were excluded from the system. The benchmarking data also demonstrated the potential to identify more eligible candidates for clinical trials in real-time if scaled up to the whole health system and importantly suggest the potential for significantly increased enrolment of underrepresented minorities.

Future Studies: Aim 1 - Confirm core algorithms improve efficiency of clinical trial patient matching (CTPM) while maintaining accuracy when scaled up to include Smilow New Haven as well as our Care Center Network.

We will conduct prospective studies on matching patients who will visit YNHH (Fairfield/Trumbull campus, North Haven campus, main campus GI, and Main campus Breast) during a 6-month timeframe for two clinical trials (HIC 2000027242 and HIC 2000029678) in two different trial centers (GI cancer and Breast cancer). Similar to our preliminary work, we will measure 1) efficiency improvement by using our CTPM system compared to manual chart review, 2) accuracy of matching potential candidates to trials compared to human review, and 3) the changes in volume of screening patients after using our system. Acceptance criteria: Performance in identifying candidates for pilot clinical trials with average accuracy over 80% and specificity over 80%; Reduction in screening time by 50%; Increase volume of screening patients by 100%.

Aim 2: Demonstrate CTPM system results in identification and accrual of more patients onto clinical trials. Within the same 6-month timeframe of Aim 1 and for the same clinical trials at same sites, we will have our clinical trial coordinator (CTP) use the CTPM system to identify eligible patients and recruit, then we will compare the number of identified and recruited patients to the prior 6-month timeframe which was based on manual referral-based workflow. Acceptance criteria: Using CTPM system can help identify at least 20% more eligible patients and recruit at least 10% more participants for clinical trials within the same timeframe.

Aim 3: Demonstrate CTPM system can help identify and recruit more underrepresented patients on to clinical trials. Within the same 6-month timeframe of Aim 1 and for the same clinical trials at same sites, we will benchmark the number of underrepresented eligible patients (Age >=65 yrs or Race is non-white) identified by CTPM system and further recruited, then we will compare the number of identified and recruited underrepresented patients to the prior 6-month timeframe which was based on manual referral-based workflow. Acceptance criteria: CTPM system can help identify at least 20% more, and recruit 10% more underrepresented patients within the same timeframe.

Expected Outcomes We will demonstrate that the CTPM is able to pre-screen a large patient cohort to identify subjects suitable for clinical trials in multiple disease areas. This will prove that it can be used as a clinical decision support tool with high accuracy and scalability. Long Term Impact With CTPM as the new standard method in clinical trial patient recruitment, we will help the cancer center improve the efficiency of clinical trial patient screening, increase the rate of clinical trial awareness for both patients and providers, and increase the rate of clinical trial accrual.

Reference
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