Category: Clinical Trial Operations – Work in Progress

Establishing a Pre-Screening Process – Creating the Right Tool

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1. Background
Clinical trial recruitment can be a common struggle for many clinical trials offices. In fact, meeting study accrual goals can become a balancing act of managing resources and staff time. With busy clinics, investigators often rely on research nurses and coordinators to find candidates for clinical trials through pre-screening mechanisms. Historically, the UAMS clinical trials office (CTO) has used spreadsheets, paper logs, and disease-specific databases to track pre-screening activities. However, the lack of an organized process has led to missed study enrollments and a loss of valuable time and effort. Additionally, our office needed a way to identify trends and gaps in underperforming trials to examine barriers to trial recruitment. Collection of this data is important to guide future recruitment efforts. As a growing CTO with 260 studies across 14 disease groups, it was essential to find an efficient tool that could be utilized uniformly across our disease teams.

2. Goals
1. Redesign a previously developed system called the pre-screening system (PSS) to meet the current needs of our operations team
2. Use PSS to document/track pre-screening activities and status of potential study candidates across all studies
3. Create study and disease group reports to monitor pre-screening activities
4. Configure PSS to alert study staff when a candidate is added into the portal

3. Solutions and Methods
In 2015, CTO staff collaborated with the information technology research systems team at UAMS to build an application for prescreening called PSS. Unfortunately, the system went underutilized due to its complexity. Rather than build a new application, the two teams decided to redesign PSS to meet our current needs. Early on, the teams met to outline the desired workflow and define the required data elements for the system rebuild. At each phase of development, PSS underwent user testing to evaluate performance of the product and guide the redesign.

Specifications for the new version of PSS:
- Integrated with the electronic medical record (EMR); to add a patient into PSS, the user can search by patient name, medical record number, or clinic schedule
- Upon entry into PSS, patients are categorized in three pre-screening categories: pending, declined, or accepted
    - Pending status indicates staff are waiting on information to complete the review (e.g., lab/pathology reports, etc.)
    - Declined status indicates the patient was found unsuitable for the trial
    - Accepted status indicates the patient will move forward to sign consent and start screening

- Each category is equipped with dropdown menus and comment fields to allow staff to document details about each status
- Study staff track and communicate the status to investigators

4. Outcomes

With the first phases of the project complete, we are working on our implementation plan. As we begin to implement the system on a broader scale, the operations team has designated a small group of staff to complete additional testing and function as training leads.

5. Lessons Learned and Future Directions

The collaboration with our IT partners is ongoing while we continue developing the reporting and auto-notification mechanisms of PSS and focus on continually improving the system.